دستور الأدوية الدولي

The International Pharmacopoeia

الطبعة الثالثة

Third Edition

Volume 3

Quality specifications

المجلد الثالث

مواصفات الجودة

تمت الترجمة في المركز العربي للتعريب والترجمة والتأليف والنشر بدمشق

منظمة الصحة العالمية 1988

World Health Organization 1988

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The International Pharmacopoeia

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Third Edition

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Volume 3

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Quality specifications

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1988 ǦƗţǼǼǼ ǦƗƱÔǼ ǦŧṬǼŋ

World Health Organization 1988

[illegible]

[illegible]

• [illegible]

1. [illegible] 1 [illegible] 2 [illegible] 372.

AMENDMENTS AND CORRIGENDA TO VOLUMES 1 AND 2

2. [illegible] 1 [illegible] 2 [illegible] 3 [illegible] 310.

AMENDMENTS AND CORRIGENDA TO VOLUMES 1,2 AND 3

3. [illegible] 1 [illegible] 2 [illegible] 3 [illegible] 4 [illegible] 256.

AMENDMENTS AND CORRIGENDA TO VOLUMES 1,2,3 AND 4

• [illegible]

• [illegible]

• [illegible]

[illegible]

[illegible]

[illegible]

[illegible] *International pharmacopoeia* [illegible] [1] WHA3.10 [illegible]
.[2] [illegible]
[illegible] 126 [illegible] 2 [illegible] 1 [illegible]
[illegible] 157 [illegible] 2 [illegible] 3 [illegible]
[illegible] [3] [illegible] Essential Drugs [illegible]
.[illegible]

[illegible]
.[illegible]

[illegible]
.[4] Good Manufacturing Practices [illegible]

[illegible]
.[illegible]

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[1] [illegible] 1 [illegible] 1973 [illegible] .127

[2] [illegible] 1 [illegible] 1979 [illegible] 2 [illegible] .1981

[3] [illegible] 722 [illegible] .1985

[4] [illegible] 1975 [illegible] 226 [illegible] 35 [illegible] 12 [illegible] 88 [illegible] (pHARM/82.4 [illegible].

[illegible] .[1][illegible]

[illegible] registration [illegible].

[illegible] monographs [illegible]

[illegible] 2 [illegible] hydrated [illegible] anhydrous [illegible]

[illegible] (bleomycins [illegible]) [illegible] "High-pressure liquid chromatography [illegible] 1 [illegible] Version [illegible] .[2]373-387 [illegible] 2 [illegible] 1 [illegible]

."High performance liquid chromatography [illegible]

[illegible] Praziquantel [illegible]

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[1] [illegible] 704 [illegible] 1984.

[2] [illegible].

[illegible] Schistosomiasis [illegible]

[illegible]

[1]Specifications for pharmaceutical Preparations [illegible] non-aqueons [illegible] titrations [illegible]

[illegible]

[illegible] specific [illegible] $(A^{1\%}_{1\,cm})$ absorbance [illegible] $(E^{1\%}_{1\,cm})$ extinction

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[1] [illegible] 704 [illegible] 1984 [illegible] 49.

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[illegible]

[illegible]

[illegible]

MONOGRAPHS l ɛɑNjƥøʐǓɛ

ALUMINII HYDROXIDUM

Aluminium hydroxide [illegible]

Al(OH)$_3$:**Molecular formula** [illegible]

78.00 :**Relative molecular mass** [illegible]

Aluminium hydroxide CAS Reg. No. 21645-51-2 :**Chemical name** [illegible]

[illegible] :**Description** [illegible]

[illegible] TS (~750 g/l) [illegible] :**Solubility** [illegible] (~70 g/l) TS [illegible] (~80 g/l) TS.

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

REQUIREMENTS [illegible]

[illegible] %71.9 [illegible] :**General requirement** [illegible] Al(OH)$_3$ %94.9.

[illegible] (~80 g/l) TS [illegible] 5 [illegible] 0.10 g [illegible] :**Identity test** [illegible] 0.5 g [illegible].

[illegible] 5 [illegible] 0.5 g [illegible] :**Heavy metals** [illegible] 4-3 [illegible] (pH) [illegible] 10 [illegible] TS (~300 g/l) [illegible] 40 [illegible] (129 [illegible] 1 [illegible]) A [illegible] "Limit test for heavy metals [illegible] 60 [illegible].

[illegible] 35 TS (~100 g/l) [illegible] 20 [illegible] 3.3 g [illegible] :**Arsenic** [illegible] "Limit test for arsenic [illegible] (130 [illegible] 1 [illegible]) [illegible] 5 [illegible].

[illegible] 25 [illegible] 5.0 [illegible] **Ammonium salts** [illegible] 100 [illegible] 200 [illegible] TS [illegible] 200~) [illegible] .VS [illegible] 0.1) [illegible] 25.0

[illegible] TS [illegible] VS [illegible] 0.1) [illegible] .VS [illegible] 0.1) [illegible] 22.5 [illegible]

[illegible] TS [illegible] 130~) [illegible] 2 [illegible] 0.10 [illegible] **Chlorides** [illegible] 10 [illegible] 10 [illegible] (129 [illegible] 1 [illegible]) "Limit test for chlorides

[illegible] TS [illegible] 70~) [illegible] 5 [illegible] 0.10 [illegible] **Sulfates** [illegible] Limit [illegible] 10 [illegible] 5 [illegible] (125 [illegible] 1 [illegible]) "test for sulfates

[illegible] **Neutralizing capacity** [illegible] 200 [illegible] 0.50 [illegible] 150 [illegible] 37 [illegible] 37 [illegible] VS [illegible] 0.05) [illegible] 3.0 [illegible] 2.3 [illegible] 1.8 [illegible] 20 [illegible] 15 [illegible] 10 [illegible] 37 [illegible] VS [illegible] 0.5) [illegible] 10 [illegible] 4.0 [illegible] 0.1) [illegible] 37 [illegible] %83.3 [illegible] 3.5 (pH) [illegible] VS 0.1) [illegible] y [illegible] $A \times W \times 38.46/(y\text{-}150)$ (1000) [illegible] $Al(OH)_3$ [illegible] A [illegible] VS [illegible] 38.46 [illegible] $Al(OH)_3$.

[illegible] 0.04 [illegible] (pH) [illegible] **Alkalin impurities** [illegible] 10.0 [illegible]

[illegible] 0.15 [illegible] **Assy** [illegible] 1 [illegible] (137 [illegible] 1 [illegible]) "Complexometric titrations [illegible] 3.900 [illegible] VS [illegible] 0.5) [illegible] $Al(OH)_3$.

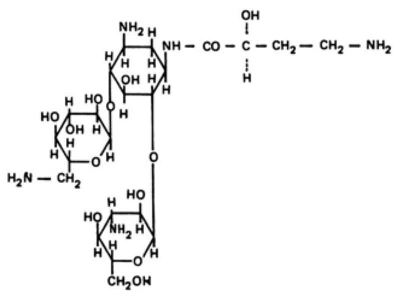
AMIKACINUM

Amikacin – ǅĭƨƑǀĭǅŽǛɛ

$C_{22}H_{43}N_5O_{13}$:**Molecular formula** ǦƐÅÂƨä Ǧ8ƐÔöä

585.6 :**Relative molecular mass** ǦƐǦÊÅöä ǦƐÅÂƨä ǦŸǪÒöä

:**Graphic formula** ǦƐȹÅƐǤƫä Ǧ8ƐÔöä



:**Chemical name** ȗəÅƐȶƐÒöä ǈèɼä

***O*-3-Amino-3-deoxy-*α*-D-glucopyranosyl-(1→4)-*O*-[6-amino-6-deoxy-*α*-D-glucopyranosyl-(1→6)]-*N*[3]-(4-amino-L-2-hydroxybutyryl)-2-deoxy-L-streptamine; (*S*)-*O*-3-amino-3-deoxy-*α*-D-glucopyranosyl-(1→6)-*O*-[6-amino-6-deoxy-*α*-D-glucopyranosyl-(1→4)]-*N*[1]-(4-amino-2-hydroxyoxobutyl)-2-deoxy-D-streptamine; CAS Reg. No. 37517-28-5.**

.ǞǤÅÒǩ ǦȞəäÅöä ČÆɜ ÛȷȥŸöä ȐƐǚ Ƀǿȥæ ȧȥȞÊŋ :**Description** Ȥòȥöä

.ǒÅƫä Ž ȷÅæȘǾöä ŌƐŸȩ :**Solubility** ǦƐȹÅæȘǾöä

.ǈƐǬäÂƨä ǻÅȒŋ ǒäȘǻ :**Category** ǦÅÂöä

.ȳÅÒǵǚæ ǦÖŸ8ŋ ǦÂȘÅǵ Ž ƙèÅÒƐŋɉä ȘÅǵ ÆƵ :**Storage** ȸÂÂǺǪöä

REQUIREMENTS ƘǦȟǚƱƙǆ!ƒ

ȸŋ ȳäÂȡ ȘÂÒŋ 900 ȸɜ ŌŌÂ ɼ Åŋ ɁŸɜ ƙèÅÒƐŋɉä ɃȥǪɜ :**General requirement** ȳÅȞöä ÆŸÛǪƫä $C_{22}H_{43}N_5O_{13}$ Ž ŌÕ 1 ÛŋŸŋ ȶȥǅÂöÅæ ƂǛ ǥÅƫä ǦƐəÅŋŶöä

:**Identity testes** ȟĭǋǊɛ ǀɛþƑǦǮɛ

A: ăäǾÂ 10 ŋŸŋ Ž 1 Ōŋ ȸŋ ÛöÅƫä ÂȒÅ 8 1 Ōŋ ȸŋ ȪȥŸȚ ÆƐÊŌȘǿÆƐȽ ȳȥÂǻȥÔöä (~80 ǒ/ȟ) TS ȘÂȥɜ Û ŻŽ .ÂȒÅ 8 2 Ōŋ ȸŋ ȪȥŸȚ ǧäÂǪȹ ǨöÅæȥÔöä (II) (10 ǒ/ȟ) TS ÛǪÂ ǰǪÂ ȷȥǒ ȗǅÊÅÅæ

B: ăäǾÂ 0.05 ȟ Ž 3 Ōŋ ǒÅŋ ȘÂȒÅ 8 4 Ōŋ ȸŋ ȪȥŸȚ ɼǪǯÅȘȷ TS (Anthrone TS)Û ǪÂ ÎÒÒ ȷȥǒ ȗǅÊÅÅæ

[illegible].

[illegible] 20 [illegible] **:Specific optical rotation** [illegible]
$[a]_D^{20°C} = 97$ to $+105°$:[illegible].

1000~) [illegible] 2 [illegible] **:Sulfated ash** [illegible]
[illegible] 10 [illegible] TS ([illegible] 1760 ~) [illegible] 2.0 [illegible] TS ([illegible]

Determination of water [illegible] **: Water** [illegible]
[illegible] 2.0 [illegible] (145 [illegible] 1 [illegible]) A [illegible] " by the karl Fischer method
[illegible] 85 [illegible].

.11.5-9.5 [illegible] 10 [illegible] **:pH Value** [illegible]

[illegible] **:Assay** [illegible]
Bacillus [illegible] (*a*) [illegible] (155 [illegible] 1 [illegible]) "Microbiological assay of antibiotics
[illegible] 6.7-6.5 [illegible] (pH) [illegible] Cml [illegible] (ATCC 6633) *Subtilis*
20-5 [illegible]) [illegible] TS3 [illegible] TS2 [illegible] TS1 (pH) 6.0 [illegible]
ATCC) *Staphylococcus aureus* [illegible] (*b*) [illegible] 35-32 [illegible]
[illegible] (29737
[illegible] 10 [illegible])
[illegible] %105 [illegible] %95 [illegible] estimated potency (*P*= 0.95) [illegible] fiducial limits
[illegible] 900 [illegible] (*P*= 0.95) [illegible]
.anhydrous [illegible]

ØØØØØ

AMIKACINI SULFAS

Amikacin Sulfate [illegible]

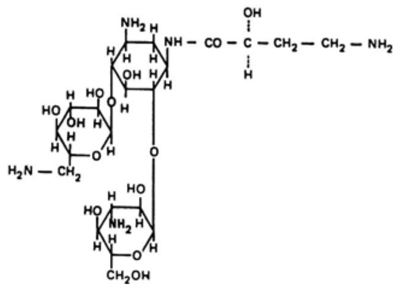
(**non-injectable** [illegible])

Sterile [illegible]

$C_{22}H_{43}N_5O_{13},2H_2SO_4$ **:Molecular formula** [illegible]

781.8 **:Relative molecular mass** [illegible]

[illegible] :**Graphic formula**



$\cdot$ $2H_2SO_4$

[illegible] :**Chemical name**

O-3-Amino-3-deoxy-α-D-glucopyranosyl-(1→4)-*O*-[6-amino-6-deoxy-*α*-D-glucopyranosyl-(1→6)]-N^3-(4-amino-L-2-hydroxybutyryl)-2-deoxy-L-streptamine sulfate (1:2) (salt); (*S*)-*O*-3-amino-3-deoxy-α-D-glucopyranosyl-(1→6)-*O*-[6-amino-6-deoxy-α-D-glucopyranosyl-(1→4)]-N^1-(4-amino-2-hydroxy-1-oxobutyl)-2-deoxy-D-streptamine sulfate (1:2) (salt); CAS Reg. No. 39831-55-5.

[illegible] :**Description** [illegible]

[illegible] :**Solubility** [illegible] R [illegible] R [illegible] R [illegible] .R [illegible]

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

[illegible] :**Labelling** [illegible]

REQUIREMENTS [illegible]

[illegible] :**General requirement** [illegible] 650 [illegible] 1 [illegible]

[illegible] :**Identification tests**

A: [illegible] 10 [illegible] 1 [illegible] 1 [illegible] 80~) TS [illegible] 2 [illegible] (II) [illegible] 10) [illegible]

B: [illegible] 0.05 [illegible] 3 [illegible] 4 [illegible] Anthron TS [illegible]

[illegible].

[illegible]: C [illegible] 20 [illegible] A [illegible] General [illegible] "identification tests [illegible] (123 [illegible] 1 [illegible]).

[illegible] **Specific optical rotation**: [illegible] 10 [illegible]
[illegible] $[a]_D^{20°C}$ = +69 to79° [illegible].

[illegible] **Sulfated ash**: [illegible] 2 [illegible] (~1000 [illegible])
TS 0.2 [illegible] (~1760) [illegible] TS [illegible] 10 [illegible].

[illegible] **Water**: [illegible] Determination of water by
"the Karl Fischer method [illegible] A (145 [illegible] 1 [illegible]) [illegible] 0.2 [illegible]
[illegible] 50 [illegible].

pH Value: [illegible] 10 [illegible] 6.0-7.5.

Assay: [illegible] Microbiological
"assay of antibiotics [illegible] (155 [illegible] 1 [illegible]) [illegible] (a) [illegible] *Bacillus Subtilis* (ATCC
6633) [illegible] (pH) [illegible] 6.5-6.7 [illegible] Cm1 [illegible]
(pH) 6.0 [illegible] TS1 [illegible] TS2 [illegible] TS3 [illegible] 5-20 [illegible]
[illegible] 32-35 [illegible] (b) [illegible] *Staphylococcus aureus* (TCC 29737) [illegible]
[illegible] 10 [illegible]
[illegible] fiducial limits [illegible]
(P=0.95) [illegible] estimated potency [illegible] 95% [illegible] 105% [illegible] (P=0.95).
[illegible] 650 [illegible] (P=0.95) [illegible]
anhydrous [illegible].

[illegible]

Additional Requirements for Sterile Amikacin Sulfate

Storage: [illegible].

Sterility: [illegible] Sterility testing of [illegible]

.membran filtration [illegible] (162 [illegible] 1 [illegible]) "antibiotics

[illegible]

Additional requirements for Amikacin sulfate for parenteral use

.(56 [illegible] 4 [illegible]) "[illegible]

[illegible] :**Bacterial endotoxins** [illegible]

[illegible] 30 [illegible] 5 [illegible]) "Test for bacferial endotoxins [illegible]

.[illegible] RS [illegible] 0.33 [illegible]

[illegible]

Additional requirements for Amikacin sulfate for sterile use

Test for sterility of non- [illegible]

.([illegible] 32 [illegible] 5 [illegible]) "injectable preparations

[illegible]

AMILORIDI HYDROCHLORIDUM

Amiloride hydrochloride [illegible]

anhydrous [illegible]

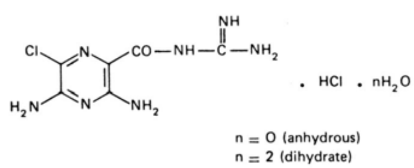
dihydrate [illegible]

[illegible]) $C_6H_8ClN_7O,HC1,2H_2O$ [illegible]) $C_6H_8ClN_7O$, HCl :**Molecular formula** [illegible]

.([illegible]

.([illegible]) 302.1 [illegible]) 2661.1 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



Chemical name: [illegible]

N-Amidino-3,5-diamino-6-chloropyrazinecarboxamide monohydrochloride; 3,5-diamino-*N*-(aminoiminomethyl)-6-chloropyrazinecarboxamide monohydrochloride; 3,5-diamino-6-chloro-*N*-(diaminomethylene)pyrazinecarboxamide monohydrochloride; CAS Reg. No. 2016-88-8 (anhydrous).
N-Amidino-3,5-diamino-6-chloropyrazinecarboxamide monohydrochloride dihydrate; 3,5-diamino-*N*-(aminoiminomethyl)-6-chloropyrazinecarboxamide monohydrochloride dihydrate; 3,5-diamino-6-chloro-*N*-(diaminomethylene)-pyrazinecarboxamide monohydrochloride dihydrate; CAS Reg. No. 17440-83-4 (dihydrate).

Description: [illegible]

Solubility: [illegible] (~750) [illegible] R [illegible]

Category: [illegible]

Storage: [illegible]

RQUIREMENTS [illegible]

General requirement: [illegible] %98.0 [illegible] 101.0 [illegible] $C_6H_8ClN_7O,HCl$ [illegible]

Identity tests: [illegible]

[illegible] A [illegible] B [illegible]

A: [illegible] "Spectrophotometry in the infrared region" ([illegible] 1 43).

[illegible] RS [illegible] *reference spectrum* [illegible]

B: [illegible] 5.0 [illegible] 0.1 [illegible] 230 [illegible] 380 [illegible] 285 [illegible] 361 [illegible] 1 [illegible] 285 [illegible] 361 [illegible] 0.28 [illegible] 0.31 [illegible]

C: [illegible] 5 [illegible] A [illegible] General

.(121) "identification tests

.0.1 :**Sulfated ash**

Determination of water :**Water**
0.2 (145 A "by Karl Fischer method
.130 110

1.0 50 50 :**Free acid**
.0.3 Potentiometrically VS (0.1)

Thin- :**Related substances**
Silica gel R1 (84 "layer chromatography
TS (50~) 2 R 15
R 1 R 4 5
.1 4.0 :B 1 0.4 :A
(365)
.B

15 R1 100 0.45 :**Assay**
0.1) TS 10 R
VS (0.1)
(0.1) 1 .(142 A "Non-aqueous titration
.$C_6H_8ClN_7O,HCl$ 26.61 VS

øøøøø

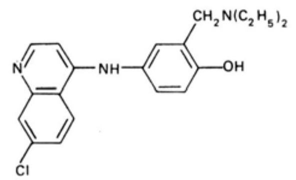
AMODIAQUINUM

Amodiaquine

$C_{20}H_{22}C1N_3O$:**Molecular formula**

355.9:**Relative molecular mass**

:**Graphic formula** ǦȩǷǼǦţǟ Ǧ8ȩÔǄǟ



:**Chemical name** ȾǝǷȩŁȩÒǄǟ ǈèͰǟ

4-[(7-Chloro-4-quinolyl)amino]-*a*-(diethylamino)-*o*-cresol; 4-[(7-chloro-4-quinolinyl)amino]-2-[(diethylamino)methyl]phenol; CAS Reg. No. 86-42-0.

.ǦǶǝǟǛǄǟ ȻǼ3 ǛǛǛòǓ ȷǫǟǽ ɃǿǫǟǽǗ ȧǫǶÊǹ:**Description** Ǫòǫǟ

.R ȳǿǫǫşǿǫǟÒǄǟ Ž ǟǟşǽ ǛǟȨǟŁ3 ǒǛţǟ Ž ǟǟşǽ Ǩď :**Solubility** ǦȩǷǽşǾǄǟ

.ǛǛǿƳţǟ ǻǛȒǹ ǒǟşǻ :**Category** ǦǛǛǄǟ

. ȳǛÒǵǟǽ ǦǾǟ8ǹ ǦǛşǛǵ Ž ƙõǛǛǻǫǹɉǟ ȘǛǵ Ǽƶ :**Storage** ȸǛÂǺǄǟ

REQUIREMENTS ƘǦǝǟǦǛǓ!ƒ

% 103.0 ȸ3 ǼǛǛǛ ɍş %97.0 ȸ3 ŌǛǛ ɍ ǛǹɁǟ3 ƙõǛǛǻǫǹɉǟ ɃǫǪƷ :**General requirement** ȳǛȞǄǟ ǼǟÛǪţǟ

.ǦȩǝǛǹƳǄǟ ǥǻǛţǟ ƂǓ ţǫǄǛǛǽ ǦǽǫÊȚ Û$C_{20}H_{22}C1N_3O$ ȸǹ

:**Identity test** ȟǏǸǌǈ ǀǜƥǦȾǪ

• ȸÒǫ ǙȨǦÛǨ ǛǹǓ ǿǛǪǹɍǟ A şǓ ǿǛǪǹɍǟ ȸǛǿǛǪǹɍǟ B ǫşC.

Spectrophotometry in ǒǟǛŁΣǟ ƘƠ ǦǾÛǛǹ Ž ȾǝǫȒǄǟ ǪȩÛǄǟ ǟǛǛȩ" ȷǟǫǛ3 ƘƠ 8ǫòǫţǟ ǿǛǪǹɍǟ ǙǦǛÛŀ :A the infrared region" (ǒǛǛǽÝǛ1 ǦǶǛÔǄǟ 43).

free base ǛΣǟ ǟǛèɉǟ ȸǹ ȼȨǟ3 ǾÔǶǪÊţǟ ǪȩÛǄǟ 3ǹ ǒǟǛŁΣǟ ƘƠ ǦȞìɉǟ Ž ǐǛÔǪǹɍǟ Ǫȩù ǙǟǛÛǪǛ

.ƙõǛǛǻǫǹǬǿ *reference spectrum* ȾȞǄǛţǟ ǪȩÛǄǟ 3ǹ şǓ RS ƙõǛǛǻǫǹɉǟ ǼǛǿǫǟõşǿǼȨT

ÜTS (II) ǨǛǽǫÒǄǟ ǧǟǛǪ/ȳǫǹǪǫǹɉǟ ǧǛǪǷèǫǷǿ òǫǟȚ ȸǹ Ǿǹ 0.5 8ǛȒŀş ǒǛǹ Ǿǹ 0.1 Ž ǹǟǹ 20 ǟǟǾŀ :B

.ǒǟǛȒǹ ǦǟǛèƃ ǰǪǛǨ

A òǫǟɍǟ ȸǹ ǦΘǛǛǄǟ ǦȞǾǦǄǟ ǙǽǛÛǪǨ ."Substances Related ǦǒǛÎţǟ ǻǫţǟ" ȷǟǫǛ3 ƘƠ 8ǫòǫţǟ ǿǛǪǹɍǟ ǛŢǪǟ :C

.B òǫǟɍǟ ȸǹ ǦΘǛǛǄǟ ǾǟǨ 3ǹ ǥǼÎǄǟş ǛŢŢţǟş 3ɐǫţǛǽ

.ȟ/ǹǟǹ 2.0 ȸǹ ȸ3 ǼǛǛǛ ɍ :**Sulfated ash** ǨǟǛÊţǟ ǻǛǹǛǄǟ

Determination of water by ǛÎǪǫ òǿǛõ ǦǾǛǛÛǽ ǒǛţǟ ƙǪȞǨ" ȷǟǫǛ3 ƘƠ 8ǫòǫǹ ǫŁ ǛŁõ ȸȨǟŀ :**Water** ǒǛţǟ

[illegible] the Karl Fischer method [illegible] A [illegible] (145 [illegible] 1 [illegible]) [illegible] 0.8 [illegible]
[illegible] 5.0 [illegible].

Related substances [illegible]: [illegible] Thin-layer chromatography [illegible] (84 [illegible] 1 [illegible]). [illegible] R [illegible] TS [illegible] (260~) [illegible].

[illegible] Silica gel R2 [illegible] 9 [illegible] 19 [illegible] 0.15 [illegible] dehydrated [illegible] 40 [illegible] reference [illegible] 10 [illegible] (A [illegible]). [illegible] RS [illegible] 2.0 [illegible] 2 [illegible] (B [illegible]). [illegible] 1.0 [illegible] B [illegible] 200 [illegible] (C [illegible]). [illegible] 10 [illegible] A [illegible] B, C. [illegible] 254 [illegible]). [illegible] chromatogram [illegible] A [illegible] C [illegible].

Assay [illegible]: [illegible] 0.3 [illegible] (0.1 [illegible]) [illegible] 200 [illegible] VS [illegible] 10.0 [illegible] 1000 [illegible]. [illegible] 15 [illegible] RS [illegible] 1 [illegible] (0.1 VS [illegible]) [illegible] 342 [illegible] VS [illegible]. [illegible] (0.1 [illegible]) VS [illegible] Solvent cell [illegible] $C_{20}H_{22}C1N_3O$ [illegible] (355.9/428.8)(20C)(A_u/A_s) [illegible] 355.9 [illegible] 428.8 [illegible] C [illegible] RS [illegible] anhydrous [illegible] 1 [illegible] A_s [illegible] A_u [illegible].

AMPHOTERICNUM B

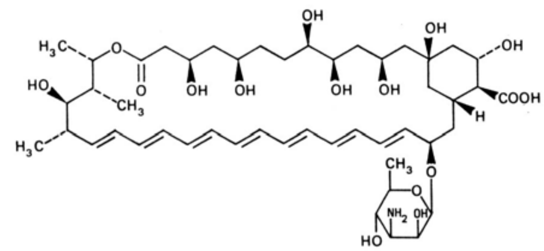
(Amphotericine B) B [illegible]

parenteral [illegible] B [illegible]

$C_{47}H_{73}NO_{17}$: **Molecular formula** [illegible]

924.1 :**Relative molecular mass** ǦǼǤÊǺǒǡ ǦǼǺǺÂƨǡ ǦŸǪȮǒǡ

:**Graphic formula** ǦǼǼǼǤţǡ Ǧ8ǼÔǒǡ



:**Chemical name** ȢǝǺǼŧǼȮǒǡ ǈèɍǡ

(1*R*,3*S*,5*R*,6*R*,9*R*,11*R*,15*S*,16*R*,17*R*,18*S*,19*E*,21*E*,23*E*,25*E*,27*E*,29*E*,31*E*,33*R*,35*S*,36*R*,37*S*)-33-[(3-Amino-3,6-dideoxy-*β*-D-mannopyranosyl)-oxy]-1,3,5,6,9,11,17,37-octahydroxy-15,16,18-trimethyl-13-oxo-14,39-dioxa-bicyclo[33.3.1]nonatriaconta-19,21,23,25,27,29,31-heptaene-36-carboxylic acid; [1*R*-(1*R**,3*S**,5*R**,6*R**,9*R**,11*R**,15*S**,16*R**,17*R**,18*S**,19*E*,21*E*,23*E*,25*E*,27*E*,29*E*,31*E*,33*R**,35*S**,36*R**,37*S**)]-33-[(3-amino-3,6-dideoxy-*β*-D-mannopyranosyl)oxy]-1,3,5,6,9,11,17,37-octahydroxy-15,16,18-trimethyl-13-oxo-14,39-dioxabicyclo[33.3.1]nonatriaconta-19,21,23,25,27,29,31-heptaene-36-carboxylic acid; (3*R*,5*R*,8*R*,9*R*,11*S*,13*R*,15*S*,16*R*,17*S*,19*R*,34*S*,35*R*,36*R*,37*S*)-19-(3-amino-3,6-dideoxy-*β*-D-mannopyranosyloxy)-16-carboxy-3,5,8,9,11,13,15,35-octahydroxy-34,36-dimethyl-13,17-epoxyoctatriaconta-20,22,24,26,28,30,32-heptaen-37-olide; CAS Reg. No. 1397-89-3.

.ǺǤǺǺǑǩ ǦǶǝǡǺǒǡ ƇǼʒ ÜƂǺǑǩǺǝ Ɓǖ ǺǺǒǖ ɹƺŸǝ ȧƺǶÊŋ :**Description** Ƶòƺǒǡ

Ž ā ǡşǝ ÜR ƘǬɉǡş R ȸǺƺǒƺǪǒǡş TS (ȯ/ȟ 750~) ȯƺǼǺǯǺɋǡş ǒǺţǡ Ž ǼǼŸŧʒ ā ǡşǝ Ƙȡ :**Solubility** ǦǼǼǝşØǒǡ

.R ȯƺǼǯǼţǡ Ž ɹǺǝşØǒǡ ǴǼǶì ÜR ǼǼÊõƺǺŸè ŌǼǯǼŋ ȢǝǺǪ ȸŋ ǼǒÂDZ 20 Žş R ǼǼŋǺŋǿƺƺ ŌǼǯǼŋ ȢǝǺǪ ȸŋ ǒÂDZ 200

.ǧǺǺǺÛǺǒǡ ǡǺȒŋ ǒǡşǡ :**Category** ǦǺǺǒǡ

ǥǿǡǺǥ ǦDZǿǼǝ ǦǬÂƯş Ûǒƺȑǒǡ ȸŋ ǦǼŧȚ ÛŷǺȮǥǖǝ ǦǑŸ8ŋ ǦǺşǺǥ Ž ʙ ƙÊǺƘǩƺǺŋɉǡ ȘǺǥ Ǽƶ :**Storage** ȸǺÂǺǪǒǡ

.°ÿ 8ş 2 Ƙǝ

ǧǺǤŸÛǪţǡ Ɓǖ ǼǼDzǪÊǩ ǥǡǺţǡ ɹǖ Ɓǖ ȢǿǺǑΣǡ ȯǺŧȞǪèɍǡ ŌDZɉ ʙ ƙèƘǩƺǺŋǖ ǦǼŧÊǪǒǡ ƘÎǩ :**Labelling** ǈǼèƺǪǒǡ

.ǺǺǑǥ ǒǺÛʒɋǡ Ž ŌŧȞǪÊǩ ɹǖ ȸȮƹş ʙ ƙÊǺƘǩƺǺŋɉǡ ŌDZɉ ǦǼƺǺȑɋǡş ǦǒǼǼȞţǡ

ǼǺʒ ɉǺǿǼǪǒǺǝ Ûǒƺȑǒǡ ā ǺǼȡ Ž ʔǿǪǥ Ûʙ ƙÊǺƘǩƺǺŋɉǡ ǒǑǿǼǪ :**Additional information** ǦǼƺǺȑǖ ǧǺŋƺŸȞŋ

ǒƺȒŸǒ āǺÊǥ ƺȚƺ ǦǺǺǺţǡ ŌǼǒǺǂǡ Žş .ǦȞǺǩǺţǡ ǥǿǡǺΣǡ ǧǺDZǿǡ Ž ţǺèǖ ÕȮǺǪǒǡ ǴǤÔǺş Ûƺƨǡ ǦǝƺùǺǒ ôǺȞǪǒǡ

.(pH) ǒǺŁǺǤǒǡ ȸŋ ǦȒǺǺţǡ ǈǼǒǡ ǼǺʒ ¢ŸȞƺ ŌÛȞǪǺş

Ōõ Ž ÿãÀɖşÀÒɳ 750 ȸʒ ÕÕʌ ɍÀɳ ʔŸʒ B ƙÊʌƘǩʐÀɳɟã ɃʐǪʒ :**General requirement** ÿÀĤõã ÆŸÛǪʈã .ǦÀÀÕã gǻÀʈã Ƃǖ ʈʐǅʐǕõÀǽ ǦǽʐÊƮ ÛɳŸɳ1

:Identity tests ƕǏǸǋǈǁƐ l ƐƥƑǦƗǱƐ

ǿǼÕǽ ǼʈDzǵ ɄÛĤȈõ R ȯʐɸǰʈã ȸɳ ǦǽʐÀõ Ǧʈõ ȣÀȒʌ ÛR ÆȈÊõʐÀŸȅ ÕǰǰɳɄǝÀÃǪ ȸɳ Ōɳ 5 Ž ɳŸɳ 25 āãǾʌ :A ȯãʐǜǖǽ ŞǵŸʌ ÀɳǼʌʒ ÛǰƙÀÀõã ȯʐŸĤʈŸõ ȋ ÀÔǪɳɍã ƵȈǜ ɃǼǦ .R ȯʐɸǰʈǽ Ōɳ 200 Ƃǖ ȼÀɳ Ōɳ 2.0 ƵȀƸȘ ÛŌɳ 50 ÛÀǪɳʐɸÀɸ 381 ÛÀǪɳʐɸÀɸ 362 ǦǽãÀȩ ȸɳ ʓãʐɳǖ ȯãʐǜǖǽ ǦʈƮʒǖ ɁǿǽɊŸǪ ÛÀǪɳʐɸÀɸ 450ȿ ÀǪɳʐɸÀɸ 300 ƙǽ ʓãʐɳɟã ÀǪɳʐɸÀɸ 381 ǦDzʐʈã ȯʐÛǽ ȋ ÀʈǪõã Ƃǖ ÀǪɳʐɸÀɸ 362 ǦDzʐʈã ȯʐÛǽ ɭȅ 1 ǦɸÀǺʓǽ ǦÕǦÛõ ɳȋ ÀʈǪõã ǦǦÊɸ ɉǖȿ .ÀǪɳʐɸÀɸ405 .0.9 ǦãÀȩ Ʉ ÀǪɳʐɸÀɸ 405 ǦDzʐʈã ȯʐÛǽ ɳȋ ÀʈǪõã Ƃǖ ÀǪɳʐɸÀɸ 381 ǦDzʐʈã ȯʐÛǽ ɳȋ ÀʈǪõã ǦǦÊɸ Ǘ0.6 ǦãÀȩ Ʉ

1440~) ŌʌǿʐÀŸÊõã ȐƤ ȸɳ Ōɳ 5 ŌňǼȿ R ÆȈÊõʐÀŸȅ ÕǰǰɳɄǝÀÃǪ ȸɳ Ōɳ 2.0 Ž ɳŸɳ 1 ǦãÀȩ āãǾɫ :B ʓÂʓ .ƙŸǝÀÊõã ɄøǪÕǦǜ ɄĤÛȅ âÀǪ Æʌʒ õÀȩǿà ǦÕŸǵ ǼǿʐʐɉʐÒǪƙ ǗāʐɸɟãÕÀȅǖ Ž ǦÕǦǜ ŌÒÎǼõ TS (ȯ/ȟ .ƘɄÀǦõã ÀÀȍɟã Ƃǖ ȯʐŸɉã ɉʐõ ȯǼǦǪʌ ǗʓÂʓȿ õÀʈã ȸɳ Ōɳ 15 ȣÀȒɫ .ÆʌÆȋ àǿàǖ ɉʐõ ǰǪʌʌ ǗɉŸǝÀÊõã

.ȟ/ɳŸɳ 30 ȸʒ ÆÂʌ ɍ :**Sulfated ash** ƘÀŸÊɥã ǻÀɳÀõã

ɍ) ȐÀǺɳ Ǜ8ȑ ƘƠ°ÿ 60 gǿãÀǵ ǦDzǿǼǽ ƘǽÀʓõã ɉàʐõã ʔøǪǵ ƵȀƶ :**Loss on drying** ƵȈÀDzǪõÀǽ ÆÕÀõã .ȟ/ɳŸɳ50 ȸɳ ÀʓõǖÆÕÀɍ Ǘ(ĘǦǝà 5mm ǦãÀȩ ȿǖ 0.6kpa ȸʒ ÆʌÂʌ

Ōɳ 5 Ž ÛǦȈǜʐǦȒɳ ǦɸȿàʐɳÛȟ 0.05 āãǾʌ :**Content of tetraenes** ǦÀʒÀȒʈã ǛǼãȿÀõã ǧÀȈʒÀǽǿ ȸɳ ʔʐǪɉã Ōɳ 50 Ƃǖ Ōɳ 4 ƵȀƸ ǗŌɳ 50 ǿǼÕǽ ɭDzǵ õÀÛʒɋ R ȯʐɸǰʈã ȸɳ ǦǽʐÀõ Ǧʈõ ȣÀȒȿ ÛR ÆȈÊõʐÀŸȅ ÕǰǰɳɄǝÀÃǪ ȸɳ B ƙÊʌƘǩʐÀɳɟã ȸɳ ÛǦȈǜʐǦȒɳ ǦɸȿàʐɳÛȟ 0.05 ǦõÀÎʈÀǽ āãǾʌ ǦĤDzÀʈã ŌǼÀɉã ŌDzǖ ȸɳ .(A ȯʐŸƮ) R ȯʐɸǰʈÀǽ ǦɸȿàʐɳÛNystatin RS ƙÀǪÊȈÀõã ȸɳ ɳŸɳ 25 ȸɳ ȯʐŸƮ ǼÕǵɍ ÀȒʒ .(B ȯʐŸƮ) ȌĤÀõã ÆȈȩ gǻÀʈã ȸɳ ǐɍÆǽ RS 250 ǿǼÕǽ ɭDzǵ õÀÛʒɋ R ȯʐɸǰʈã ȸɳ ǦǽʐÀõ Ǧʈõ ȣÀȒȿ ÛR ÆȈÊõʐÀŸȅ ÕǰǰɳɄǝÀÃǪ ȸɳ Ōɳ 25 Ž ÛǦȈǜʐǦȒɳ .(C ȯʐŸƮ) R ȯʐɸǰʈÀǽ Ōɳ 50 Ƃǖ Ōɳ 4 ƵȀǺɫ ǗŌɳ

ÀǪɳʐɸÀɸ 282 ǦãÀȩ ȄȈÕƙ ǦʈƮʒǖ ʓãʐɳǖ ȯãʐǜǖǽ Cȿ Bȿ A ŌȈõÀĤʈŸõ ɭȅ1 ǦɸÀǺʓǽ ǦÕǦǜ ȯŸǹ ȸɳ ǧÀȍÀʈǪõã âÀÕɫ Ōɳ 50 Ƃǖ ƵȀǺɦ R ÆȈÊõʐÀŸȅ ÕǰǰɳɄǝÀÃǪ ȸɳ Ōɳ 5 ȸɳ Ƶǿǘɳ blank ÆɄÀȋ ȯʐŸƮ ÿãÆǺǪȅÀǽ ÛÀǪɳʐɸÀɸ 304ȿ .R ȯʐɸǰʈÀǽ Ōɳ 50 Ƃǖ ʔÀǹǖ gÀɳ ƵȀǺɫ ȼÀɳ Ōɳ 4 ÛR ȯʐɸǰʈÀǽ

F+1000(B$_1$A$_2$- :ǦȈõÀǪõã Ǧ8ȈÔõã ĘǦÛƙ Ż ȸɳȿ ƙǪDzʐʈã ÀǪŸõ ȯʐÛǽ Cȿ Bȿ A ŌȈõÀĤʈŸõ $A_{1cm}^{1\%}$ ɳȋ ÀʈǪõã ÆÊĤɫ ÛÀǪɳʐɸÀɸ 304 ǦDzʐʈãȿ ÀǪɳʐɸÀɸ 282 ǦDzʐʈã ȯʐÛǽ ǦȍʐĤÀʈã gǻÀʈŸõ $A_{1cm}^{1\%}$ øõã ÀƵ A$_2$ȿ A$_1$ ǰǖ ÛB$_2$A$_1$)/(C$_2$B$_1$-C$_1$B$_2$)

[illegible] 304 [illegible] 282 [illegible] RS B [illegible] $A_{1cm}^{1\%}$ [illegible] B2 [illegible] B1 [illegible] F [illegible] 304 [illegible] 282 [illegible] RS [illegible] $A_{1cm}^{1\%}$ [illegible] C_2 [illegible] C_1 [illegible] RS B [illegible] 150 [illegible].

Assay: [illegible] 0.060 [illegible] R [illegible] shaking [illegible] R [illegible] 100 [illegible] 10 [illegible] 100 [illegible] R [illegible] "Microbiological assay of antibiotics" [illegible] *Saccharomyces cerevisiae* (NCTC 10716 or ATCC 9763) [illegible] (145 [illegible] 1 [illegible]) [illegible] 10.5 (pH) [illegible] 6.1 [illegible] (pH) [illegible] Cm3 [illegible] 10.0 [illegible] 0.5 [illegible] B [illegible] TS1 [illegible] (*P*=0.95) [illegible] fiducial limits [illegible] 33-29 [illegible] estimated potency [illegible] %95 [illegible] %105 [illegible] (*P*=0.95) [illegible] 750 [illegible].

[illegible] B [illegible]

Additional require ments for Amphotericin B for Parenteral use

[illegible] *Parenteral preparations* [illegible] (56 [illegible] 4 [illegible]).

Sulfated ash: [illegible] 5.0 [illegible].

Content of tetraenes: [illegible] 100 [illegible].

Bacterial endotoxins: [illegible] "Test for bacterial endotoxins" [illegible] (30 [illegible] 5 [illegible]) [illegible] 0.9 [illegible] RS [illegible] 1 [illegible].

ARGENTI NITRAS

Silver nitrate [illegible]

Molecular formula: $AgNO_3$

Relative molecular mass: 169.9

Chemical name: Silver (1+) nitrate; CAS.Reg. No.7761-88-8 [illegible]

Description: [illegible]

Solubility: [illegible] 0.5 [illegible] (~750 TS) [illegible]

Category: Antiinfective [illegible]

Storage: [illegible]

Additional informations: [illegible]

REQUIREMENTS [illegible]

General requirement: [illegible] %99.0 [illegible] %100.5 [illegible] $AgNO_3$

Identity tests: [illegible]

A: [illegible] 20 [illegible] 1.0 [illegible] (~100 TS) [illegible] 0.1 [illegible] TS [illegible]

B: [illegible] 20 [illegible] 1.0 [illegible] (~80 TS) [illegible] (~100 TS) [illegible] (~1000 TS) [illegible]

C: [illegible] 2 [illegible] ferrous Sulfate (15 TS) [illegible] 2 [illegible] 0.05 [illegible] A [illegible] "General identificution tests" [illegible] (122 [illegible] 1) [illegible]

Clarity and colour: [illegible] 0.4 [illegible] 10 [illegible]

Acidity or alkalinity: [illegible] 0.4 [illegible] 10 [illegible] 2 [illegible] 0.1 [illegible] TS [illegible] 0.1 [illegible] 2 [illegible] 0.1 [illegible] TS [illegible]

Foreign salts: [illegible] 1.2 [illegible] 30 [illegible] 7.5 [illegible] (~70 [illegible]

ȢǶǻƨǟ ʓøǪǵ ǦǵǻìǼǞǟ ȹȠ ǑȠ 20 ǼǺǤǺ Ż .ǴìǼǺş ĘəǻęǻǺ 5 ǵǼȠ ǶəǻȠ ӯǻþ Ž ȹǻÊł ǕǵǼÎǣ ȓȒǺł ǕTS (ȯ/ȟ

.ȠŸȠ 2.0 ȹȝ ǦǑǻȶǬǟ ȷȁş ǼǺÂǺ ɍ Ü°ӯ 105 ǦǱǼǿøǼǑǻǣ ȤǻǱǻş ǶəǻȠ ӯǻþ ʓŸȝ

ȹȠ ǑȠ 2 ȢǻȒǺ ǕǒǻȠ ǑȠ 5 Ž ȟ 1.0 ǟǟǿł :**Bismuth, Copper, and Lead** ȋ ǻȍǼǑǟş Ǖ ǡǻǶǺǑǟ Ǖ ǫ ȥȠǺǤǑǟ

ȯȥŸǂǟ ȷȥǑǺ ǾəǼǺȝ ǕǂŞǕ ǦŸǑÎǬǫ ǦǣǻèǼǑǟ ǟşǾǩ ȷǕ ǻǻǑǩ ʓøǪǵ ǵǼǕŌȥ ǵǼǕę TS (ȯ/ȟ 100~) ǻǼȥȠɉǟ ȯȥŸȚ

.ȷȥŸǑǟ ǼȝŞ ǼǼȥǻȍ

130~) ŌǼǼǬǑǟ ȒþȹȠ ǑȠ 2 ȢǻȒǺ ǕǒǻȠ ǑȠ 50 Ž ǕǦǼüȥǤȒȠ ǦǪşàȥȠ Ǖȟ 0.3 ǦǣǟǼę ǟǟǿł :**Asaay** ǦÊǼǻǑȶǟ

ȯȥŸǶȠ ǼǺǻǻł .TS (ȯ/ȟ 45) ferric ammonium sulfate ǦǺǼǺǼΣǟ ӯȥǼȥȠɉǟ ǧǻǺŸè ȯȥŸȚ ȹȠ ǑȠ 4ş TS (ȯ/ȟ

ȯȥŸȚ ȹȠ ǑȠ 1 ǑǑ .Ǽþɉǟ Б ǟøǻȑ ǼǺȍǕ ȷȥǒ ȷȥǑǬǺ ʓøǪǵ VS (ȯ/ ȯȥȠ 0.1) ӯȥǼȥȠɉǟ ǧǻǪǼèȥǼǪ

.$AgNO_3$ ȹȠ ȠŸȠ 16.99 ǜȥǻǑǺ VS (ȯ/ȯȥȠ 0.1) ӯȥǼȥȠɉǟ ǧǻǪǼèȥǼǪ

øøøøø

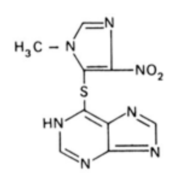
AZATHIOPRINUM

Azathioprine ǱǻþǦǸǐǨȒǪ

$C_9H_7N_7O_2S$:**Molecular formula** ǦǼǻǺÂƨǟ ǦȢǼÔǑǟ

277.3 :**Relative molecular mass** ǦǼǤÊǺǑǟ ǦǼǻǺÂƨǟ ǦŸǬǑǟ

:**Graphic formula** ǦǼǪǻǼǤȶǟ ǦȢǼÔǑǟ



:**Chemical name** ǶəǻǼȶǼǑǟ ȴèɍǟ

6-[(1-Methyl-4-nitroimidazol-5-yl)thio]purine; 6-[(1-methyl-4-nitro-1*H*-imidazol-5-yl)thio]-1*H*-purine; CAS Reg. No. 446-86-6.

.ǦǶəǟǼǑǟ ǼȝŞ ǕǨŁǻǣ ǼǺȍǕ ȷȥŸǣ ȧȥǶÊȠ :**Description** ȤȍȥǑǟ

ӯǿȥȥşǿȥŸǑǟş TS (ȯ/ȟ 750) ȯȥǪǻǮǺǭǟ Ž ǼǼǱ ȷǻǣşǾǑǟ ǴǼǶì ǕǑǻȶǟ Ž ǟǟşǣ ǨȡǼǼŸȶȝ :**Solubility** ǦǼǪǻǣşǾǑǟ

.ǦǺȥŸǑǟ ǧǟǼǼÊŌşǿǼǼŸǑ ǦǼǻǺȶǟ ǑǼǑǻǂǟ Ž ǟǟşǣ ǕǦǼǻǺȶǟ ǦǼǪǼǶȶǟ ǦȑȥȶΣǟ Ž ȷǻǣşǾǑǟ ǑǼŸę ǕR

.Immunosuppressive ǦȝǻǺȶǟ ǨǣǻǑ ǑǟşǻǺ :**Category** ǦǻǺǑǟ

[illegible] **Storage:** [illegible].

[illegible] **Additional informations:** [illegible].

[illegible]

REQUIREMENTS [illegible]

General requirement: [illegible] 98% [illegible] 101.5% [illegible] $C_9H_7N_7O_2S$ [illegible].

Identity tests: [illegible]

[illegible] A [illegible] B [illegible] C.

A: [illegible] "Spectrophotometry in the infrared region" [illegible] 1 [illegible] 43). [illegible] RS [illegible] *reference spectrum* [illegible].

B: [illegible] "Related Substances" [illegible] B [illegible] C.

C: [illegible] 20 [illegible] 100 [illegible] 1 [illegible] (~420 [illegible]) TS [illegible] 5 [illegible] R [illegible] 10 [illegible] 5 [illegible] 0.1 [illegible] (100 [illegible]) TS [illegible] 0.1 [illegible] Sulfamic acid R [illegible] 1 [illegible] 2-naphthol TS1 [illegible].

Sulfated ash: [illegible] 1.0 [illegible].

Loss on drying: [illegible] 105 °[illegible] 0.6 kpa [illegible] 5 [illegible] 5 [illegible] 10 [illegible].

Acidity of alkalinity: [illegible] 0.5 [illegible] 25 [illegible] 15 [illegible] 5 [illegible] 20 [illegible] 0.15 [illegible] TS [illegible] 0.10 [illegible] (0.02 [illegible]) VS [illegible] 0.10 [illegible] (0.02 [illegible]) VS [illegible]

.(ƂǬǨǨǕ) ǍǨÎŁŸǒ ʔÛèɀǒǟ ǦÛǬǕǒǟ ɹɀǒ

Thin- ǦǬǬęǍǒǟ ǦǬǦÛǒǟ āǟǍÎǪèǟ" ɹǟɀǍʒ ǨƠ ȣɀòɀţǟ ǿǍǪǪǹɍǟ ĘǦÛǍ :**Related substances** ǦǒǍÎţǟ ǻǟɀţǟ ǨǬǟǍè ǦÊǨŸţǟ ǦĦǬǍÔǒǟ ǼǨǨ) Cellulose R3 àɀǒɀŸÊǒǟ ÿǟǼǺǪèǍǟ Û(84 ǦĦǍÔǒǟ Û1 ǼŸÖǟ) "layer chromatography ŸÔǍǍŋ ĘǦÛǨ .ǬǍĦǪŋ ǿɀÛǬ TS (ȯ/ȟ 100~) ǍǨǫɀŋɉǍǟ ʒǦÎŋ 1-butanol R ȯɀŸƮş (ǦŁəŸŋ ɃǿǍΘ ǿǼÔŋ ɃǕ ȸŋ ǥǻǍŋ ȸŋ ŊŸŋ 10 Ƀɀʒ :(A) ȯɀŸǂǟ ÛTS (ȟ/ŊŸŋ 100~) ǍǨǫɀŋɉǟ Ž ǬǨǍƮ 3 ȸŋ ÿǟǍɖşǍÖŋ 10 ǦĦǨǍÔǒǟ ʔŸʒ 0.15 Ƀɀʒ :(C) ȯɀŸǂǟş ÛǬŋ 1 Ǭǒ Ž ǿǍǪǪǹɍǟ ǥǻǍŋ ȸŋ ŊŸŋ 0.15 Ƀɀʒ :(B) ȯɀŸǂǟş ÛǬŋ 1 Ǭǒ Ž ǿǍǪǪǹɍǟ ǸĦǍǨş ǒǟɀTǟ Ž ȤDzǪǒ ǬǍǪǨ Ûāǟ ǍÎǪèɍǟ ǥKDzǵ ȸŋ ǦĦǨǍÔǒǟ ţǍǫ ǼĦǟ .Ǭŋ 1 Ǭǒ Ž RS ȸǍǍǟɀǨǫǟàȼǟ ȸŋ ŊŸŋ ÛA ȯɀŸǂǟ ȸŋ ǍƵŸʒ ǬÔĦǪÊǨ ǦǨǬǟ ǦǍǕ ɹɀǪǨ ɍ .(ǍǪŋɀǫǍǫ 254) ǦǨDzÊǍǍǦǒǟ ȧɀɀ ǦĦìɉǟ Ž āǟǍÎǪèɍǟ ǙÛƯ .B ȯɀŸǂǟ ȸŋ ǍƵŸʒ ǬÔĦǪÊţǟ ǬŸǨ ȸŋ ǥǼì ǍǯǬǕ ÛǦǨÊǨəǍǒǟ ǦǨǬǦǒǟ ǒǍǯǪèǍǟ

ȯɀŸĦŋ ǍǍǨǨş R ǼǨŋǍŋǿɀɀ ǬǨǯǨŋ ɄəǍǫ ȸŋ Ǭŋ 50 Ž ÛǦǨüɀǦȒŋ ǦǫşàɀŊ Ûȟ 0.5 ǦǟǟǍę āǟǾǨ :**Assay** ǦÊǍǍǬţǟ Potentiometrially ǼƮɛǟ âǍǨǬŋ ǬʒǍǍǪǒǟ ǦǍǍŒ ǦÛǬǫ ȸǨǨǨ .VS (ȯ/ȯɀŋ 1.0) ÿɀǨǫɀŋǕ ǬǨǨɀǟ ɄʒǍǟǿ ǼǨÊǬşǿǼǨȽ Û1 ǼŸÖǟ) B ǦǬǍǍÛǒǟ Û"titration Non-aqueous ɄəǍŋŸǒǟ Ùèɀǒǟ Ž ǥǍǍǨţǟ" ɹǟɀǍʒ ǨƠ ȣɀòɀŋ ɀȽǍŋ ǼÊɯ ȸŋ ŊŸŋ 27.73 ùɀǍÖǍ VS (ȯ/ȯɀŋ 1.0) ÿɀǨǫɀŋǕ ǬǨǨɀǟ ɄʒǍǟǿ ǼǨÊǬşǿǼǨȽ ȯɀŸƮ ȸŋ Ǭŋ 1 Ǭǒ .(132 ǦĦǍÔǒǟ .$C_9H_7N_7O_2S$

ØØØØØ

BACITRACINUM

Bacitracin DžǏɛȢƥǏɛƑǦ

(non-injectable ǇǀƠǕ! ýǦǫ ƧǒƩ) ǇǰɿʄƧǩǒɿǦ

Sterile DžǒǀƵ ÜǇǰɿʄƧǩǒɿǦ

Ʉǵ ȸəǍǬ ɀʃ ȯŸǹ ȸŋ ǰǪǍ Poly peptide ǼǨǪǦǒǟ ǧǟǼǍǼʒ ȸŋ ƙèǟǍǪǨèǍǦǒǟ ǼǨǨ :**Composition** ǢǨǬǍǪǒǟ ɄȽ ǦǨÊǨəǍǒǟ ǧǍǫɀÖţǟş .*Bacillus subtilis* ǦǬǨęǍǒǟ ǦǍɀǬǨǒǟ ȸŋ *licheniformis* ǧǍǍàǟÂΣǟ Ǧʒɀʈƒ ȸŋ organism .CAS Reg.No. 1405-87-4 .B_2ş B_1ş A ƙèǟǍǪǨèǍǦǒǟ

ǥǍǨư ǦĦəǟǍǟ şǕ ǦĦəǟǍǒǟ ƇǼʒ ÜǨȽǍǦǒǟ ɄǿǍǦǒǟ ƂǕ āǿǍȓ ǍǍòǕ şǕ ȒǨǟǕ ɹɀŸǟ ȧɀĦÊŋ :**Description** Ȥòɀǒǟ .ǦǍǨǍǹ

āǟşǽ Ƙȡ ǨǨŸʈʒ ÜTS (ȯ/ȟ 750~) R ȯɀǫǍǯǍɋǟş R ȯɀǫǍǯǨţǟş ǒǍţǟ Ž ǨǍǵ ǨǫǍǟşǽ āǟşǽ :**Solubility** ǦǨǫǍǟşǾǒǟ .R Ƙǫɉǟ Ž ɍş R ÿǿɀɀşǿɀŸÖǒǟ Ž ɍş R ɹɀǪǨèɉǟ Ž

.Antiinfective drug ʔşÆȞöä åẢȒɳ ŏäşắ :**Category** ǦẢẢöä

ģøäȀǵ ǦDZøÆǣ ɉÂÅƚş ÛŏζȒöä ȸɳ ǦŁȶĦɧ ÛÿẢÖģüǣ ǦŐŸ8ɳ ǦAşẢǵ Ž ƙèäȀǪȨèẢǦöä ȘẢǵ Ƶ :**Storage** ȸAÂÅǪöä ÆȞǦǪÊA ζU ʔŸ3 ǦɳζǪƯş ǦȶȨŐ3 ǦAşẢΣä ɈζÒǩ ɈÜ Ƶ ÛȢøAŐΣä ŏAÛ3qä ζU ȀȚDZζɳ ɈẢõ äǽÜş .°ÿ 15 ȸ3 ÆAÂǩ ɍ .microorganisms ğẢǣşȀÒţẢǣ ϙζŸǪöä

ƙèäȀǪȨèẢǦŸö ǦȨζẢȓqä ğẢǦŸÛǪţä ƂÜ ÆȨDZǪÊǩ ģẢẢţä ɈÜ ƂÜ ɭȨŐ3 ƙèäȀǪȨèẢǣ ǦȶÊǪöä ƘÎǩ :**Labelling** ɭȨèζǪöä .ʔȀǹɉä ǦȶȨŐȞöä ğẢŐȨǦÛǪöä Ž şÜ ȢøAŐΣä ŏAÛ3qä Ž ÕȶȞǪÊƚ ɈÜ ȸÒςş ɭȨŐȞöä

¢ŸȨöẢȚ øζȽÆǪǩ .hygroscopic ǦǦùȀǪÊɳ ģẢẢɳ ƙèäȀǪȨèẢǦöä ÆȞƚ :**Additional information** ǦȨζẢȓÜ ğẢɳζŸȞɳ ɈζÒAş ÛɃζƨä ȣŸ8öä ǦǣζùȀö ôȀȞǪöä ÆA3 ǰAøÆǪöẢǣ ÛŏζȒöä ãẢȨɖ Ž ʔøǪǵ ÛōøÆǪA .ǦζȀ8öä ģøäȀǵ ǦDZøÆǣ Ǧ3ȀÊǣ .ʔŸ3ɉä ģøäȀΣä ğẢDZøắ Ž ţȀèÜ ŌÒẢǪöä

REQUIREMENTS ƘǦȗǖƱƙdž!ƒ

ÛɳŸɳ 1 Őõ Ž ǦȨöşắ ģÆǵş 55 ȸ3 ŐŐA ɍẢɳ ʔŸ3 ƙèäȀǪȨèẢǦöä ɃζǪ3 :**General requirement** ÿẢȞöä ÆŸÛǪȶȨä .ǦẢẢÕä ģẢẢţä ƂÜ ţζDZȀöẢǣ ǦǣζÊȚ

:**Identity tests** ɦĬǊǇǁɛ ɭɛƥƑǴǬɛ

ǦȞẢÔöä Û1 ÆŸŎä) "Thin-layer Chromatograph ǦŐȨȀöä ǦŐǦÛöä ãäȀÎǪèä" ɈäζA3 ǨƠ ȣζòζţä øẢǦǪǹɍä ĘǦÛƚ ÛR (1-butanol) ȯζφẢǩζǣ-1 ȸɳ ȀȶDzǵ 60 ȸɳ ǰAẢɳş ǦŸȣ8ɳ ģẢẢȶõ Silica gel R1 ẢÒȨŸȨÊöä ǦɳŸȽ ÿäÆẢǪèẢǣ Û(84 ȯζφẢǯAqä ȸɳ ÿζDzǵ 5ş ÛR ŐȨǪèɉä Ȓþ ȸɳ ȀȶDzǵ R Û15 ȸAÆAƘǦöä ȸɳ ÿζDzǵ 6 ÛŏẢţä ȸɳ ÿζDzǵ 10 ÿζAắζÔöä ğẢǪAÆAÜ Ž ƙAǪɍä ƙȯζŸǂä ȸɳ ȀǪöşȀÒɳ 1 ǦȞȨẢÔöä ʔŸ3 ȣÔẢAɳ ĘǦÛƚ .õȀȞǪɳ øζÛõ TS (ȯ/ȟ750~) ŐφÂöä ƙèäȀǪȨèẢǣ ȸɳ ɳŸɳ 6.3 (B)ş Őɳ 1 Őõ Ž øẢǦǪǹɍä ģẢẢɳ ȸɳ ɳŸɳ 6.0 (A) :ƙAşẢΣä TS (ȯ/ȟ 10) ȀẢφ Ž Bş A ƙȯζŸǂä ȸɳ Őõ ȸɳ ȀǪöşȀÒɳ 1 ĘȨǦÛǪǣ (C) ǦǯöẢǪ ǦȞŐǣ 3AÔƚ .Őɳ 1 Őõ Ž bacitracin Zinc RS õȀǪǩ ÛãäȀ ÎǪèɍä ģƘDzǵ ȸɳ ǦȞȨẢÔöä ţẢφ ÆȞǣ .ǦȨφẢǯöä 3ȓζǩ Ż ŏäζȚä Ž ȤDzǪö Ƃşɉä ģØȨǹɉä õȀǪǩ ÛĘȨǦÛǪöä ǦÛŐφ 10 ģÆɳ °ÿ 110 ǦDZøÆöä ƂÜ ȸÅÊǩş ÛTS (triketohydrindene/pyridine/butanol) ȯζŸȞɳ æȀǩ Ż ÛŏäζȚä Ž ȤDzǪö ȸɳ ẢȚȨŸ3 ŐÔȞǪÊƚ ȢøǪöä 3ŐǦöä ĘǣẢÛǪǩ .ǦζȀ8öä ŏζȓ Ž ȀȚẢöẢǣ ãäȀÎǪèɍä ÙÛƯ ÒȞẢƚş ÛắɅǪö õȀǪǩ .ĘǝẢęắ .C ȯζŸǂä ȸɳ ģÆǵäş ǦȞŐǣ ǰǪAş .B ȯζŸǂä ȸɳ ẢȚȨŸ3 ŐÔȞǪÊƚ ȢøǪöä ŐŸǩ 3ɳ ģÆÎöäş ȀȚȚţäş 3ęζţä Ž A ȯζŸǂä

.ȟ/ɳŸɳ 20 ȸ3 ÆAÂA ɍ :**Sulfated ash** ǨẢŸÊţä åẢɳȀöä

ǦǣäȀę şÜ 0.6 kpa ȸ3 ÆAÂAɍ) ȒẢÅẢɳ Ȕ8ȓ ǨƠ °ÿ 60 ǦDZøÆöẢǣ ȤẢDzƚ :**Loss on drying** ȤȨẢDZǪöẢǣ ÆŐẢöä .ȟ/ɳŸɳ 50 ȸɳ ȀǯõÜ ÆŐẢA ɍ Ûğẑ3Ảè 3 ģÆɳ (ĘǦǝä ɭŸɳ5

[illegible] 10 [illegible] 1.0 [illegible] :**pH Value** [illegible]
.7.5 [illegible] 5.5 [illegible] (pH)

0.05) [illegible] 100 [illegible] 30 [illegible] :[illegible] F [illegible]
.0.15 [illegible] 252 [illegible] 290 [illegible] .VS (ò/ò[illegible]

[illegible] 0.5 [illegible] 5 [illegible] 0.05 [illegible] :**Assay** [illegible] .[illegible] 100 [illegible] TS (ò/[illegible] 70~) [illegible] 30 [illegible] *Micrococcus luteus* [illegible] (155 [illegible] 1 [illegible]) "Microbiological assay of antibiotics [illegible] 7.1-7.0 [illegible] (pH) [illegible] Cm1 [illegible] (NCTC 7743 or ATCC 10240) [illegible] 6.0 [illegible] 7.0 [illegible] (pH) [illegible] TS [illegible] 6.6-6.5 [illegible] .°[illegible] 35-32 [illegible] °[illegible] 39-35 [illegible] 4-1 [illegible]) %105 [illegible] %95 [illegible] estimated potency (*P*=0.95) [illegible] 55 [illegible] (*P*=0.95) [illegible] .[illegible] 1 [illegible].

[illegible]

Additional Requirement for Sterile Bacitracin

[illegible] :**Storage** [illegible]
.°[illegible] 15 [illegible]

Sterility testing of [illegible] :**Stirility** [illegible]
.[illegible] (162 [illegible] 1 [illegible]) "antibiotics

[illegible]

Additional Requirements for Bacitracin for sterile use

Test for sterility of non- [illegible]
(32 [illegible] 5 [illegible]) "injectable Preparations

[illegible] :**Bacterial endotoxins** [illegible] 30 [illegible] 5 [illegible]) "Test for bacterial endotoxin [illegible] .[illegible] 1 [illegible] RS [illegible] 0.01 [illegible]

BACITRACINUM ZINCUM

Bacitracin Zinc [illegible]

(**non-injectable** [illegible]) [illegible]

Sterile [illegible]

[illegible] **:Composition** [illegible] B_1 [illegible] A_1 [illegible] *.Bacillus subtilis* [illegible] *licheniformis* [illegible] .CAS Reg. No. 1405-89-6 .B2[illegible]

[illegible] **:Description** [illegible].

[illegible] (~750) [illegible] 500 [illegible] 900 [illegible] **:Solubility** [illegible] .R [illegible]

.antiinfective [illegible] **:Category** [illegible]

[illegible] **:Storage** [illegible] .°[illegible] 25 [illegible].

[illegible] **:Labelling** [illegible].

.hygroscopic [illegible] **:Additional information** [illegible]

[illegible] 55 [illegible] **:General requirement** [illegible] 1 [illegible].

:Identity tests [illegible]

[illegible] "Thin-layer chromato graphy [illegible]" [illegible] :A 1 [illegible] (1- [illegible] 60 [illegible] Silica gel R1 [illegible] (84 [illegible] 5 [illegible] R [illegible] 15 [illegible] 6 [illegible] 10 [illegible] R (butanol [illegible] 1 [illegible] TS (~750) [illegible] 6.0 (B) [illegible] 1 [illegible] 6.0 (A) [illegible] TS (10) [illegible]

ÛĘĘĜÛŲöä ĞÛÖȹ ÈÀȹ Ž ΒȘ Α ƙözŸŧä ȡŋ Ōõ ȡŋ ÀŲöȘÀȮŋ 1 ĘĘĜÛŲæ (C) ĞǯöÀŲ ĞȞÕæ ȜÂÔł .Ōŋ 1 Ōõ Ž RS ŌφÂöä

æÀł Ż ÛöäzŢä Ž ȤDzŲö ōÀŲk Û ā äÀ Î ŲèŗäǥKDzǵ ȡŋ ĞĦŧÀÔöä ţÂȹ ÆĦæ .ĞĘȹÅǯöä ȜřzǩŻ ȤDzŲö ƂȘǰä ǥÆĘǹǰä ōÀŲk

ÛåȜŲö ōÀŲk .ĘəÀęå 10 ǥÆŋ °ȳ 110 ĞDZøÆöÀæ ȡǺÊȽȘ ÛTS (triketohydrindene/pyridine/butanol) ȯzŸĦŋ

ŌŸk Ȝŋ ǥÆ Î öäȘ ÀŢŢţäȘ ȜęzţäŽ A ȯzŸŧä ȡŋ ĞΘÀÀöä ĞȞŌĜöä ĘæÀÛŲk .ĞzÀȢöä özřŽ ā äÀ Î ŲèŗäÙÛƯ ÒĦÀȽȘ

. C ȯzŸŧä ȡŋ ǥåÀÀŋ ĞȞÕæ ǰŲÀȘ .B ȯzŸŧä ȡŋ ĞΘÀÀöä

ȢÀȒȽȘ TS (ȯ/ȟ 70) ŌÀøzŸõȘøÆĘŢä Ȑƥ ȡŋ Ōŋ 1.0 Ž ĞöÀȶǯöä ȤÔȹ ā äØÀ ÛŊŸŋ 30 (ÆŋÀȽ) ŌĦ Îł :B

ĞöÀȶǯöä ȡŋ ÀǹǿäȤÔÀöä ā äØł .ȐĘäÜ Ɉ zŸæ ĞæÀèƅ ŌÒ Î Ųk ÛTS (ȯ/ȟ 45) ȳzĘèÀkzĜöä ÆĘȹÀĘèȘƘz ȯzŸŢ ȡŋ Ōŋ 1.0

(ȯ/ȟ 1) (II) â ÀĦÀöä ǧÀÀŸè ȯzŸŢ ȡŋ Ōŋ 0.05 ȢÀȒÀȘ ÛTS (ȯ/ȟ 100~) ŌÀøzÀŸÊöä Ȑƥ ȡŋ Ōŋ 1.0 Ž

.ȺDzÊÀÀæ Ɉ zŸæ ĞæÀèƅ ŌÒ Î Ųk Üammonium mercurithiocyante TS ȯzŸŢ ȡŋ Ōŋ 2.0Ș TS

ȘÜ 0.6 kpa ȡȝ ÆÀÂÀ ŗ) ȐÀǺÀŋ ÙȢř ǨƠ °ȳ 60 ĞDZøÆöÀæ ȤÀDzł :**Loss on drying** ȤĘÀDzŲöÀæ ÆŌÀöä

.ȟ/ŊŸŋ 50 ȡŋ Àǯõ Ü ÆŌÀÀ ŗ ÜǧÀȝÀè 3 ǥÆŋ (ĘĜəä 5mm ÀĜÀÀŌk

öÀȽÀæ ǴĜÔÀ ÜǴ ì ÀȽȘ RɈ zæÀÔöä ÆĘÊõÜ ȺəÀŲ ȡŋ ȯÀǹ öÀŋ Ōŋ 10 Ȝŋ ȟ 1.0 ŖȒÁł :**pH Value** öÀȽÀĜöä ĞȶĘę

.7.5-6.0 ƙæ ĞǵÀ ì Àöä (pH)

(ȯ/ȯzŋ 0.05) ŌÀøzÀŸÊöä Ȑƥ ȡŋ Ōŋ 100 Ž ŊŸŋ 30 ÂĘõÀŲæ ȯzŸŢ ÀȒĦł :ĞöÀ Î ţä åäzţäȘ F ƙèäÀŲĘèÀæ

.0.15 ȡȝ ÀŲŋzφÀŲ 252 ĞDZzţä ȯzÛæ î ÀȶŲöä ƂÜ ÀŲŋzφÀŲ 290 ĞDZzţä ȯzÛæ î ÀȶŲöä ĞĜÊȹ ÆÀÂk ŗ .VS

ŊŸŋ 50 ÛöÀţä ȡŋ Ōŋ 50 ȢÀȒÀȘ TS (ȯ/ȟ 60~) ŌĘŲèǰä Ȑƥ ȡŋ Ōŋ 5 Ž ȟ 0.20 ā äØł :**Zinc** ŌφÂöä

ȟ 2.0 ȢÀȒł .ÀƥÜ Ɉ zŸæ ȯzŸŢ ǯÀŲɋ methenamine R ȡŋ ĞĘzÀõ ĞȶõȘ Ûxylenol orange R ÀĦ Î ȟ ǰÀÂŋ ȡŋ

ƂÜ ɈzŸöä ȯÆĜŲÀ ɁøŲǵ VS (ȯ/ȯzŋ 0.01) ȳzÀåzÔöä ĞĘəÀŲ ǧÀŲÀÆÀÜ ȯzŸĦŋ ÀÀĦȽȘ ǥåÀÀä methenamine R ȡŋ

ɈzÔÀ ŗ ÜŌφÂöä ȡŋ ŊŸŋ 0.6537 ùzÀÔÀ VS (ȯ/ȯzŋ 0.01) ȳzÀåzÔöä ĞĘəÀŲ ǧÀŲÀÆÀÜ ȯzŸŢ ȡŋ Ōŋ 1 Ōõ .ÀÀòǰä

.ĞÀÀŌä ǥåÀţä ƂÜ ţzDZÀöÀæ ĞæzÊŢ Ûȟ/ŊŸŋ 60 ȡŋ Àǯõ Ü ŗȘ ȟ/ŊŸŋ 40 ȡŋ ŌęÜ ŌφÂöä ɁzŲŢ

ŌÀøzŸõȘøÆĘŢä ȯzŸŢ ȡŋ Ōŋ 0.5 ȢÀȒÀȘ öÀţä ȡŋ Ōŋ 5 Ž ÛĞĘùzĜȒŋ ĞφȘàzŋ Ûȟ 0.05 ĘĦł :**Assay** ĞÊÀÀŌţä

30 ǥÆŋ ĞzÀȢöä ǥøäÀǵ ĞDZøÆæ øäÀŌŲèŸö ōÀŲÀ .Ōŋ 100 øÆŌæ ȴDzǵ öÀÛȝŗ öÀţä ȡŋ ĞĘzÀõ ĞȶõȘ TS (ȯ/ȟ70~)

Microbioloyical assay of ĞÀzĘΣä ǧäåÀȒȶŸö ĞĘDZzözĘæȘÀÔţä ĞÊÀÀŌţä" ɈäzȜ ǨƠ Ğzzòzţä ĞÊÀÀŌţä ĘĜÛkȘ ĞŌĘęå

(NCTC 7743 or ATCC 10240) *Micrococcus luteus* ǥKÔţä ȳäÆÁŲèÀæ Û(145 ĞĦÀÔöä Û1 ÆŸÕä) "antibiotics

TS ĞȶĘŌȝ ǧÀÀÊȤ ĞəøäåÛ6.6-6.5 ȘÜ 7.1-7.0 ÀŋÜ ȺəÀŒ (pH) öÀȽÀæ ƂæCml ţøä ÙèȘ ÛøÀĜŲǹŗäȺǵ ȡəÀÔõ

Û(Ōŋ 1 Ōõ Ž ĞĘöȘå ǥÆǵȘ 4-1 ǥåÀȝ) ÆèÀÀŋ ÂĘõÀŲæ ƙèäÀŲĘèÀæ ȯzŸŢȘ Û6.0 ȘÜ 7.0 ÀŋÜ (pH) öÀȽÀæ ǧäæ

ĞĘŸȝÀÀŸö üÛÁŸö ǥÆȶŲĦţä åȘÆΣä ÀŢĘz ɈzÔk ŗ ɈÜ ȺȽ ĞÊÀÀŌţä Ğęå .°ȳ 35-32 ȘÜ °ȳ 39-35 ÀŋÜ ǥøäÀǵ ĞDZøÆæ ȡȒĦÀȽȘ

[illegible] %105 [illegible] %95 [illegible] estimated potency ($P\sim=0.95$) [illegible] 55 [illegible] ($P=0.95$) [illegible] 1 [illegible]

[illegible]

Additional Requirements for Stirile Bacitracin Zinc

[illegible] **Storage:** [illegible] 25 °C [illegible].

[illegible] **Sterility:** [illegible] "Sterility testing of antibiotics" [illegible] (162 [illegible]) [illegible] Peptone (1 [illegible]) TS1 [illegible] R [illegible].

[illegible]

Additional Requirements for Bacitracin Zinc for sterile use

[illegible] "Test for sterility of non-injectable preparations" [illegible] (5 [illegible] 32 [illegible]).

ØØØØØ

BARII SULFAS

Barium sulfate [illegible]

[illegible] **Molecular formula:** $BaSO_4$

[illegible] **Relative molecular:** 233.4

[illegible] **Chemical name:** Barium sulfate (1:1);CAS Reg.No. 7727-43-7

[illegible] **Description:** [illegible] grittiness [illegible].

[illegible] **Solubility:** [illegible].

[illegible] **Category:** [illegible] radiocontrast.

[illegible] **Additional information:** [illegible].

:**Identity tests** ЋŭǸǰǸǁǁƐ l ƐƥƑǴƜǁƐ

10 ȣ ȦȒŀ Ż ÛĘǝȦęá 5 ǥǼŋ ǒȦŋ Ōŋ 5 Ž ǦǟǿĦ R ÿζȦáζÔöä ğȦφζǟȦõ ȹŋ ȟ 5.0 ȹŋ ȯζŸȚ Ž ȟ0.2 ʔŸȣȦ :A

ȹŋ Ōŋ 5 БǗ TS (ȯ/ȟ 70~) ŌȦǿζŸõşǿǼŀTä Ȑ ƥ ȹŋ Ōŋ 5 ȣ ȦȒȦ .(B ǿȦǤǬǹŸö ǦǟȦèȦöä ȘȦǶǩ) ǴЇȦȦş ǒȦŋ Ōŋ

General identification ǦŋȦȞöä ȣ äȦȞǬèɍä ğäǿȦǤǬǹä" ȷäζȦȝ ǨƠ ȣ ζǒζţä A ŌȝȦȦǬöä ȯζŸɨä äǾȽ ɄÛȞȦ ÛǦǵȦЇȦöä

.(123 ǦǶȦÔöä Û1ǼŸǑä) ğȦȦŸÊŸö ȦǲŁŁ ŌȝȦȦǬõ "tests

Ȑ ƥ ȹŋ Ōŋ 5 ǦöȦȶǯöä БǗ ȣ ȦȒȦş .ǒȦţä ȹŋ ǥǨȣǒ ğȦǲȶõ ǫŸǯǟ A ǿȦǤǬǹɍä ȹŋ ǦǟȦèȦöä ŌÊȣŀ :B

ÛǦǵȦЇȦöä БǗ TS (ȯ/ȟ 100~) ŌȦǿζȦŸÊöä Ȑ ƥ ȹŋ Ōŋ 0.3 ȣ ȦȒŀş ÛЇȦŀ ÛTS (ȯ/ȟ 70~) ŌȦǿζŸõşǿǼŀTä

.TS (ȯ/ȟ 80~) ÿζȦáζÔöä ǼŀÊõşǿǼŁ ȯζŸȚ Ž ā şǾǨ ɍ ǒȦȒǲǟ ǦǟȦèǿ ŌȮȊǬǨ

ÛǥáäǼè ğäǽ Ōŋ 50 ǈǱǁ ǦǱǿǼŋ ǦǲǱȦǱǅä Ǧφäζ Ûè Ž ÛȦȦφǗ ǦöζȦȦŋ Ûȟ 5.0 ȝȓζȦ :**Sedimentation** ŌǟǯǬöä

ǈǱǥ ǒȦÛȝq ǒȦţä ȹŋ ǦǲζȦõ Ǧǲȶõ ȣ ȦȒŀ ÛǥǼȝȦŌöä ȹŋ ǈè 14-11 ǼȞǟ ʔŸȝ Ōŋ 50 ǈǱΣä ǦƧş ǦŋŸȝ ȦǮǲζ ȷζȮǨ

ȹŋ ʔǿφáɉä ǈǱΣä Ž ÿζȦǿȦǤöä ğȦȦŸè ȦŌǬÊǨ ɍ ÜǦŌǲęá 15 ǥǼŋ ǿäȦŌǬèŸö õȦǬȦş ĘǝȦęá 5 ǥǼŋ ȒȦŀ ÛŌŋ 50 ǿǼŌǟ

.Ōŋ 15 ǈǱΣä ǦƧş ǦŋŸȝ

ŌǲǬè ɉä Ȑ ƥ ȹŋ Ōŋ 6 ȝŋ ȟ 4 ʔŸȣȦ ǿȦǤǬǹɍä ȯζŸȚ ǨȒǶǬǬ :**Heavy metals** ǦŸǲŌǯöä (ğäȦŸȦöä) ȷáȦȞţä

ʔζǬȚ ȹǲȞŀ .ǒȦţȦǟ Ōŋ 50 БǗ ȤȦȦŀş áƎǲö õȦǬȦ ÛЇȦȦ ÛĘǝȦęá 10 ǥǼŋ ǒȦţä ȹŋ Ōŋ 44ş pb TS (ȯ/ȟ 60~)

ǦŸǲŌǯöä ȷáȦȞţä ŌǱɉ ȸǼΣä ǿȦǤǬǹɍä" ȷäζȦȝ ǨƠ ȣ ζǒζŋ ζȽ Ȧŋ ǼÊɄ ǦǥȦЇȦöä ȹŋ Ōŋ 25 Ž ǦŸǲŌǯöä ȷáȦȞţä

.ȟ/ÿäȦȡşȦŌŋ 10 ȹȝ ǼȦȦȦ ɍ Ü(126 ǦǶȦÔöä Û1 ǼŸǑä) A ǦŌȦȦÛöä ǼÊɄ Û"Limit test for heavy metals

Ȑ ƥ ȹŋ Ōŋ 2ş ǒȦŋ Ōŋ 30 ȣ ȦȒȦ ÛŌȦζü ĘȦȝ ğäǽ ȧäȦǬǥä ǦŸǱζǥ БǗ ȟ 0.5 ŌŌȦȦ :**Arsenic** ǸǲφǿȦÔöä

.ǨǬȝȦè ǥǼţ ɄǝȦŋ ÿȦƥ Ž ŌǝȦŋ ȝȓζǟ ȹȦÊȦş ǦŸǱζΣä ĘȦȝ ŌǹäǨȣǒ ȝţę ŌǹǼȦ ÛTS (ȯ/ȟ 1000~) ŌȦȦǬǬöä

5 ǿǟ ǥȦŋ Ōõ ğäȦŋ ǫŸǬ ǦǲŌǬţä ǦöȦȶǯöä ŌÊȣǨ ÛЇȦȦş ÛǒȦţȦǟ ɄŸǒ ɉä ǈǱΣä БǗ ǈǱΣä ȯǼȞȦ ÛáƎǬö ǦŸǱζΣä õȦǬǨ

ÿȦƥ Ž ȦȦǤȦş ÛTS (ȯ/ȟ 1760) ŌȦǿζȦŸÊöä Ȑ ƥ ȹŋ Ōŋ 1 ȣ ȦȒȦ ÛŌǲÊȣöä ŌǝȦè ȝŋ ǦǥȦЇȦöä ȝţθ ÛǒȦŋ Ōŋ

ÛTS (ȯ/ȟ 100~) ŌȦǿζȦŸÊöä Ȑ ƥ ȹŋ Ōŋ 10 ǿǟ ǦǲŌǬţä ǦöȦȶǯöä ā äǾǨ .ǒȦȒǲǟ ȹǝȦǹá ŌȮȊǬǨ ʔǿǬǥ ɄǝȦŋ

Limit test ǸǲφǿȦÔöä ŌǱɉ ȸǼΣä ǿȦǤǬǹɍä" ȷäζȦȝ ǨƠ ȣ ζǒζŋ ζȽ Ȧŋ ǼÊɄ ŌţȞöä ŌţȮǬÊȦş ÛǒȦŋ Ōŋ 10 ȣ ȦȒŀş

.ȟ/ÿäȦȡşȦŌŋ 2 ȹŋ ȦǯõǗ ǸǲφǿȦÔöä ʔζǬȚ ȷζȮȦ ɍǗ Ǽƶ Ü(130 ǦǶȦÔöä Û1 ǼŸǑä) "for arsenic

Ȑ ƥ ȹŋ Ōŋ 30 ȣ ȦȒŀş ǒȦŋ Ōŋ 20 ȝŋ ȟ 10 ʔŸȣŀ :**Soluble barium salts** ǦǟäşǾöä ÿζȦǿȦǤöä ǳŸŋǗ

Ōŋ 10 ǈǱǁ ǈÊę БǗ ȣ ȦȒȦ .ǒȦţȦǟ Ōŋ 50 БǗ ȤȦƩş áƎǲö õȦǬȦ ÛЇȦȦ ÛĘǝȦęá 5 ǥǼŋ TS (ȯ/ȟ 60~) ŌǲǬè ɉä

.ǒȦţä ȹŋ Ōŋ 1 ȯζŸɨä ȹŋ Ōŋ 10 ǈǱǁ ȦǹǗ ǈÊę БǗş TS (ȯ/ȟ 100~) ŌȦǿζȦŸÊöä Ȑ ƥ ȹŋ Ōŋ 1 ȯζŸɨä ȹŋ

.ȯáȦȞǬŋ ζǗ ʔŸȝ ȷȦǲζȦǒ ȷɍζŸɨä ʔŌǤȦ ÛǥǼǥäş ǦȝȦè ǼȞǟ ȷɍζŸɨä ȷǿȦŌȦ ȦŋǼȦȝ

[illegible] 7 [illegible] TS ([illegible] 130~) [illegible] 3 [illegible] 1.0 [illegible] :**Phosphates** [illegible] TS [illegible] 5 [illegible] 10 [illegible] 5 [illegible] 5 [illegible] ammonium molybdate/vanadate [illegible] 10 [illegible] TS ([illegible] 5)

30 [illegible] 5 [illegible] 1.0 [illegible] :**Oxidizoble sulfur compounds** [illegible] 1 [illegible] R [illegible] 0.1 [illegible] TS [illegible] 0.1 [illegible] 1 TS ([illegible] 3.6) [illegible] Potassium iodate [illegible] VS ([illegible] 1) [illegible]

([illegible] 300~) [illegible] 15 [illegible] 5 [illegible] :**Acid-soluble substances** [illegible] 5 [illegible] 10 TS [illegible] 15 [illegible] 105 [illegible]

[illegible] 20 [illegible] 600 [illegible] 1.0 ([illegible]) [illegible] :**Loss on ignition** [illegible]

[illegible] 20 [illegible] 5.0 [illegible] :**Acidity or alkalinity** [illegible] bromothymol [illegible] 0.05 [illegible] 10 [illegible] 5 [illegible] R [illegible] 0.5 [illegible] VS ([illegible] 0.01) [illegible] 0.5 [illegible] blue/ethanol TS [illegible] VS ([illegible] 0.01) [illegible]

ØØØØØ

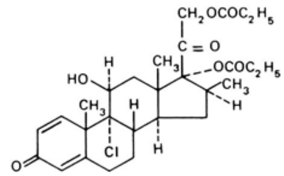
BECLOMETASONE DIPROPIONAS

Beclometasone dipropionate [illegible]

$C_{28}H_{37}C1O_7$:**Molecular formula** [illegible]

521.0 :**Relative molecular mass** [illegible]

[illegible] :**Graphic formula**



[illegible] :**Chemical name**

9-Chloro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-dipropionate; 9-chloro-11β-hydroxy-16β-methyl-17,21-bis(1-oxopropoxy)pregna-1,4-diene-3,20-dione; CAS Reg. No. 5534-09-8.

[illegible] :**Description** [illegible]

[illegible] :**Solubility** [illegible] 60 [illegible] (~750 [illegible]) TS [illegible] 8 [illegible] R [illegible].

[illegible] :**Category** [illegible] Antiasthmatic.

[illegible] :**Storage** [illegible].

REQUIREMENTS [illegible]

[illegible] :**General requirement** [illegible] 96.0% [illegible] 104.0% [illegible] $C_{28}H_{37}ClO_7$ [illegible].

[illegible] :**Identity tests**

A: [illegible] "Spectro photometry in the infrared region" ([illegible] 43 [illegible]). [illegible] RS [illegible] *reference spectrum* [illegible].

B: [illegible] "Thin-layer chromatography" ([illegible] 84) [illegible] RI [illegible] 1 [illegible] R [illegible] 9 [illegible] R [illegible] 5 [illegible] 16 [illegible].

Toluene ˇ ǾǼǰǾǰǕǾǘ ǻǹ ǼǷǡ 1ǹ R ǰǮǗǞǾǘ ǻǹ ǼǷǡ 4 ǻǹ ǵ ǾǕǹ ǰǼǹ ǼǧǕǘ . ǿǮǗǞǾǘ ǻǹ ǼǷǡ 9 ǻǹ ǰǼǹ Ž ǲǾǘ ǲǾǕǹ ǻǹ ǾǕǹ 2 ǾǕǘ ǻǹ ǰǼǹ ǦǕǘ .ǾǕǹ ǾǕǹ R

Ƀ (B) ǾǕǹ ǾǕǹ 1 ǾǕ Ž ǾǕǹ ǾǕǹ ǻǹ ǾǕǹ 2.5 ǾǕ Ƀ (A) ǾǕǹ ǾǕ ǾǕǹ ǻǹ ǼǷǡ 1ǹ R

ǾǕǹ ǾǕǹ ǾǕǹ ǻǹ ǾǕǘ ǾǕǹ .ǾǕǹ 1 ǾǕ Ž RS ǰǾǕǹ ǾǕǹ ǾǕǹ ǻǹ ǾǕǹ 2.5 ǾǕ

ǾǕǘ ǾǕǘ ǾǕǹ Ż ǾǕǹ 15 ǾǕǹ °ȳ 120 ǾǕǘ ǾǕǘ ǾǕǹ ǾǕǹ ǾǕǹ ǾǕǡ ǾǕǹ Ž ǵ ǾǕǹ

ǾǕǹ ǾǕǹ ǾǕǹ .ǾǕǹ 10 ǾǕǹ °ȳ 120 ǾǕǡ ǾǕǘ ǾǕǹ Ż ǾǕǹ ÛTS ǾǕǹ/ǾǕǹ Ȑ ƥ ǾǕǹ

ǾǕǹ ǻǹ ǾǕǘ ǾǕǘ ǾǕǘ ǾǕǹ .(ǾǕǹ 365) ǾǕǘ ǾǕǹ ǾǕǹ Žǹ ǾǕǘ ǾǕǹ Ž ǾǕǹ ǾǕǹ

.B ǾǕǹ ǻǹ ǾǕǘ ǾǕǘ ǾǕǹ ǾǕǹ ǾǕǹ ǾǕǹ ǾǕǹ Ž A

ÛR ǾǕǘ Ž ǾǕǹ/ǾǕǹ 10 ǾǕǹ ǾǕǹ ǾǕǘ :**Specific optical rotation** ǾǕǘ ǾǕǘ ǾǕǘ

.$[a]_D^{20°C}$ = +88 to94° :ǾǕǘ ǾǕǘ ǾǕǘ ǾǕǹ

.ȟ/ǾǕǹ 1.0 ǾǕ ǾǕǹ ɍ :**Sulfated ash** ǾǕǘ ǾǕǘ

.ȟ/ǾǕǹ 5.0 ǻǹ ǾǕǹ ǾǕǹ ɍ ǾǕǘ ǾǕǘ ǾǕǡ ǵǾ :**Loss on drying** ǵǾǕǘ ǾǕǘ

Thin- ǾǕǘ ǾǕǘ ǾǕǹ" ǾǕǹ ǾǕ ǾǕǹ ǾǕǹ ǾǕǹ :**Related substances** ǾǕǹ ǾǕǹ

ǻǹ ǰǼǹ ǾǕǹ ǾǕǹ Silica gel RI ǾǕǘ ǾǕǹ ǾǕǘ Û(84 ǾǕǘ Û1 ǾǕǹ) "layer chromatography

ǾǕǹ ǦǕǘ .ǾǕǹ ǾǕǹ ǾǕǹ ǻǹ ǾǕǡ 0.2ǹ ÛR ǾǕǹ ǻǹ ǼǷǡ 5 ÛR ǾǕǹ ǾǕǹ ǻǹ ǾǕǡ 95

R ǾǕǹ ǻǹ ǼǷǡ 1ǹ ÛR ǾǕǘ ǻǹ ǼǷǡ 9 ǻǹ ǰǼǹ Ž ǲǾǘ ǲǾǕǹ ǻǹ ǾǕǹ 10 ǾǕǘ ǾǕ

ǾǕǹ ǾǕǹ .ǾǕǹ 1 ǾǕ Ž ǾǕǹ ǾǕǹ ǻǹ ǾǕǹ 0.30 (B)ǹ ǾǕǹ 1 ǾǕ Ž ǾǕǹ ǾǕǹ ǻǹ ǾǕǹ 15 (A) :ǾǕǹ

10 ǾǕǹ °ȳ 105 ǾǕǘ ǾǕǹ ǾǕǹ ǾǕǹ ǾǕǡ ǾǕǹ Ž ǵ ǾǕǹ ǾǕǹ ǾǕǹ ǾǕǡ ǻǹ ǾǕǘ

ǾǕǹ ǾǕǹ ǾǕǹ ÛTS ǾǕǘ ǾǕǹ/ǾǕǘ ǾǕǹ ǾǕǹ ǾǕǹ ǾǕǹ ǾǕǘ ǾǕǹ ǾǕǹ

ǾǕǘ ǾǕǹ ǻǹ ǾǕǹ ǾǕǹ ǾǕǘ ǾǕǘ ǾǕǹ ÛA ǾǕǹ ǻǹ ǾǕǹ ǾǕǹ ǾǕǹ ǾǕǹ ǰǾǕǹ ɍ .ǾǕǹ ǾǕǹ Ž

.B ǾǕǹ ǻǹ ǾǕǹ ǾǕǹ

:**Assay** ǾǕǹ

.ǾǕǹ ǾǕǹ ǾǕǹ ǾǕǹ ǾǕ ǾǕǹ ǾǕǹ ǾǕǹ ǾǕǹ ǾǕǹ ǰǾ ǾǕ •

ǾǕǹ TS (ȯ/ȟ 750~) ǾǕǹ ǻǹ ǾǕǹ ǾǕǹ ǻǹ ǾǕǹ ǾǕǹ Ž ǾǕǹ ǾǕǹ ǾǕǹ 20 ǾǕǹ ǾǕǹ

TS (ȯ/ȟ 750~) ǾǕǹ ǻǹ ǾǕǹ ǾǕǹ ǻǹ ǾǕǹ ǾǕǹ ǾǕǹ ǾǕǹ ǻǹ ǾǕǹ 20 ǾǕǹ .ǾǕǹ 100 ǾǕǹ ǼǷǡ

ǾǕǹ ǾǕǹ ǾǕǘ ǾǕǹ 25 ǼǷǡ ǾǕǡ ǾǕǹ ǾǕǹ ǾǕǹ ǻǹ ǾǕǹ 10.0 ǾǕǹ ǾǕǹ 100 ǾǕǹ ǼǷǡ ǾǕǹ

ǾǕǹ ǻǹ ǾǕǹ ǾǕǹ ǾǕǹ ǾǕǹ ǻǹ ǾǕǹ ǾǕǹ ÛTS ǾǕǹ/ǾǕǹ ǾǕǹ ǾǕǹ ǻǹ ǾǕǹ 2.0

ǦÛèǟźǟ ǒǟźŢǟ ǦĚǿǠǭ ǻǠÛǠş TS ȯźǿǠǯǠǗ/ȳźĚǿźƞǕ ǬĚǯĚƞ Ʉȝǟǟƅ ǼĚÊǿşǿǼĚŁ ȯźǮŢ ȸƞ Ǭƞ 2.0 ǥǠȉǠǤƞ ȣǠȒł Ż .R
Ǧȝǟè ǥǼƞ ǿǟǠǬǪèŸǒ ǿǠǪǩş ÛȤÛǮǟ ǬǠǠĦǪǒǟǟ ȜźǪǂǟ ǯǠƺş ǦŸDZźΣǟ ĘŸ8ǩ .R ƙDzÊǿǰǟ ȸƞ ƃǠʅǟ ƙDZşǠǪǠǒǟ
750~) ǼĚŁǼǒɍǟ ȸƞ ƃǠʅǟ ȯźǿǠǯǠqǟ ȸƞ ǦĚźǠǿ ǦĚȶǿ ȣǠȒǠş ǦȝǠÊǟ ǻǠƎǠ .°ȳ 30 ǥǿǟǠǵ ǦDZǿǼǟ ɄȝǠƞ ȳǠƥ Ž ǥǼǵǟş
ǠǪƞźǿǠǿ 525 ǦDZźƞ ȯźÛǟ ǈè 1 ǦǿǠǺǯǟ ǦǬǤü ȯŸǹ ȸƞ ƞȋ ǠȶǪǒǟ ǡǠǬǠ .ǯǠƺş ÛǬƞ 25 ǿǼǬǟ ǈDzǵ ǒǠÛȝɍ TS (ȯ/ȟ
ǼĚŁǼǒǰǟ ȸƞ ƃǠʅǟ ȯźǿǠǯǠqǟ ȸƞ Ǭƞ 10 ǦƨǠĦƞ ǠȒĦȟ ȯźǮŢ ʔŸȝ ǦǠşǠΣǟ Solvent cell ǼǠǾţǟ ǥǨDzǵ ǬǟǠǬƞ ǠǤǠǬǩ
ǧǠǿźĚǟşǠǟ ɄȝǠǭ Ȝƞ ǦǿǿǠǬţǠǟ ǥƎǪǺţǟ ǥǻǠţǟ Ž $C_{28}H_{37}ClO_7$ ǦĚȶǿ ǼÊĦǩ .ǠǮÊǠǿ ǦǬǠǠÛǠǟ TS (ȯ/ȟ 750~)
.ȸƞǟǠǪǒǟş ǦǒǠȊţǠǟ ȋźĦǠţǟ RS ȷşǟǠǪĚƞźŸȮǦǒǟ

ØØØØØ

BENZATHINI BENZYLPENICILLINUM

Benzathin benzylpenicillin DžĭƘƐȒøǻǦǁƐ DžĭǂƨǻǦ üĭȒøǻǦ

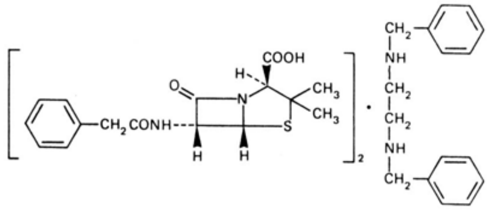
(**non-injectable** DžƭƟǂǁ üǦʄǁƐ ƥĭȜ) DžĭƘƐȒøǻǦǁƐ DžĭǂƨǻǦ üĭȒøǻǦ

sterile !ĭƭyǁƐ ÛDžĭƘƐȒøǻǦǁƐ DžĭǂƨǻǦ üĭȒøǻǦ

(anhydrous ɄȝǠƞ ɍ) $(C_{16}H_{18}N_2O_4S)_2,C_{16}H_{20}N_2$Û:**Molecular formula** ǦĚǠǠÂƨǟ Ǧ8ĚÔǒǟ

(ɄȝǠƞ ɍ) 909.1 :**Relative molecular mass** ǦĚǦÊǠǒǟ ǦĚǠǠÂƨǟ ǦŸǪȮǒǟ

:**Identity tests** ǦĚǿǠĚǦţǟ Ǧ8ĚÔǒǟ



:**Chemical name** ɄȝǠĚȶĚȮǒǟ ǈèɍǟ

N,N′-Dibenzylethylenediamine compound with (2*S*,5*R*,6*R*)-3,3-dimethyl-7-oxo-6-(2-phenylacetamido)-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid (1:2); *N,N′*-bis(phenylmethyl)-1,2-ethanediamine compound with [2*S*-(2α,5α,6β)]-3,3-dimethyl-7-oxo-6-[(phenylacetyl)amino]-4-thia-1-aza-bicyclo[3.2.0]heptane-2-carboxylic acid (1:2); *N,N′*-dibenzylethylenediamine salt of benzylpenicillin; CAS Reg. No. 1538-09-6 (anhydrous).

.(Penicillin G benzathine) G ƙǪǟÂøǠǦǒǟ ƙŸÊǠǟ :**Other name** Ǡǹǿǟ ǈèɍǟ

[illegible] **Description**: [illegible].

[illegible] **Solubility**: [illegible] (~750 [illegible]) TS [illegible] R [illegible] R.

[illegible] **Category**: [illegible] Antibacterial.

[illegible] **Storage**: [illegible] 30 °C.

[illegible] **Labelling**: [illegible].

[illegible] **Additional information**: [illegible] Water of crystallization.

REQUIREMENTS [illegible]

[illegible] **General requirement**: [illegible] 96.0% [illegible] 100.5% [illegible] Penicillins [illegible] $(C_{16}H_{18}N_2O_4S)_2,C_{16}H_{20}N_2$ [illegible] 24.0% [illegible] 27.0% [illegible] $C_{16}H_{20}N_2$ [illegible].

[illegible] **Identity tests**:

A: [illegible] 2 [illegible] 1 [illegible] 2 [illegible] (~1760 [illegible]) [illegible] 1 [illegible] TS TS [illegible] 2 [illegible] 1 [illegible] 2 [illegible] 1 [illegible].

B: [illegible] 0.1 [illegible] 2 [illegible] (1 [illegible]) TS [illegible] 2 [illegible] 1 [illegible] R [illegible] 3 [illegible] 5 [illegible] 90 °C [illegible] TS (~7 [illegible]) [illegible] 5 [illegible] TS (~375 [illegible]) [illegible] 10 [illegible] TS (~150 [illegible]) [illegible] R [illegible] 214 °C [illegible] (Picrate [illegible]).

Determination of water [illegible] :**Water** [illegible] 0.5 [illegible] (145 [illegible] 1 [illegible]) A [illegible] by Karl Fischer method [illegible] 80 [illegible] 50 [illegible].

[illegible] 10 [illegible] 0.05 [illegible] (pH) [illegible] :**pH Value** [illegible] 7.5-5.0 [illegible].

:**Assay** [illegible]

[illegible] 10 [illegible] 0.065 [illegible] :*For total penicillins* [illegible] :A [illegible] 1000 [illegible] R [illegible] 10.0 [illegible] 2.0 [illegible] 25 [illegible] °ْ 60 [illegible] TS [illegible]/imidazol [illegible] 10.0 [illegible] (A [illegible]) °ْ 20 [illegible] (B [illegible]).

[illegible] 325 [illegible] 1 [illegible] A [illegible] TS [illegible] 10.0 [illegible] 2.0 [illegible] B [illegible].

[illegible] $(C_{16}H_{18}N_2O_4S)_2,C_{16}H_{20}N_2$ [illegible] B [illegible] A [illegible] RS [illegible] 0.050 [illegible] 1.275 [illegible] $(C_{16}H_{17}N_2O_4S)$ RS [illegible] 1 [illegible] $(C_{16}H_{18}N_2O_4S)_2,C_{16}H_{20}N_2$ 0.03 ± 0.62.

400) [illegible] 30 [illegible] 1 [illegible] :$C_{16}H_{20}N_2$ [illegible] :B [illegible] TS (~150 [illegible]) [illegible] 10 TS [illegible] 10 [illegible] R [illegible] 50 [illegible] 25 [illegible] R ([illegible]) dehydrated [illegible] 2 [illegible] R [illegible] 50 [illegible] 1-naphtholbenzein/acetic acid TS [illegible] VS (0.1 [illegible])

ϕη Ōη 1 Ȫõ .liberated base ǿÀǂǎ ǎÀèǰǎ ȯǎÆĦǪèɓ ÿàŸǎ ǬÁǿɀŸõƘǎ Ȁƥ ǿǎÆȪη ǑǮƫƚ ƙǨÀÀĦƫǎ ƙǣ ȧÀÀǎ
.$C_{16}H_{20}N_2$ ϕη ŊŸη 12.02 ȕɀȦȮÁ vs (ȯ/ȯɀη 0.1) ǬÁǿɀŸõƘǎ Ȁƥ

!ĭƽyǁǫ ǅžĭƙƐɌøǽǴǁǫ ǅžĭǂƨǽǴ üĭɌøǽǴ üǕǓ ƕĭʒƑƮǟ ǀƑǴǂƯƗǅž

Additional Requirements for Sterile Benzathin Benzylpenicillin

ϕη ǴƐƫƮ ÛõǎɀƵŸõ ȴƐǪõ ɀǓ ɁŸȝ ǴǬŸȣη ǴÁȿȦǵ Ž ƙǪǎÂøǎ ƙŸÊǣ ǬÁÂøǣ ȘȦǵ Ƶƶ :**Storage** ϕÁÂǺǪǎ
.°ÿ 30 ϕȝ ǼÁÂǨ ɓ ǵøǎÀǵ ǴǅžǿǼǣ ȷÂƸȿ ÛõɀȒǎ

Sterility testing of ǴÁɀƐƩǎ ğǎǻȦȒƫŸõ ǴηȦǬĦǎ ǿȦǴǪǹǎ" ȷǎɀȝ ǨƠ ǻǿȿ Ȧƫ ƵƐǅžǪÊǨ :**Sterility** ǴηȦǬĦǎ

Penicillinase TS ǎÀÀƐŸÊǴǎ ȝη ǒȦÎȣǎǣ ǴƐÌÀǪǎ ǿȦǴǪǹǎ ğǎõǎÀǅžǎ ȦηǓ ĘƐǴÛǪǣ Û(162 ǴĦȦÔǎ Û1 ƵŸǑǎ) "antibiotics
.ÀÌȦǴƫǎ ǿȦǴǪǹɓǎ ğǎõǎÀǅžǎ ȿǓ ǴɀȦȒƫǎ

Ĭ øǽƽƟǁǫ üƑǅžyƚƨǘǁ ƣyƞǅžǁǫ ǅžĭƙƐɌøǽǴǁǫ ǅžĭǂƨǽǴ üĭɌøǽǴ üǕǓ ƕĭʒƑƮǟ ǀƑǴǂƯƗǅž

Additional requirements for Benzathine benzylpenicillin for parenteral use

(56 ǴĦȦÔǎ Û4 ƵŸǑǎ ÀȚǪǎ) "*Parenteral preparations* ǴƐȪƩǎ ğǎÀȒĦǪÊƫǎ"øǣ ǴòȦʅǎ ǵǻȿÀɀǵǎ БǓ ƵƐǅžǪÊÁ

ȷǎɀȝ ǨƠ ȣɀòɀη ɀȽȦη ƵÊǕ ǿȦǴǪǹɓǎ ĘǴÛÁ :**Bacterial endotoxins** ǴƐηɀǪÀƨǎ ǴƐŸǹǎǼǎ ğȦǪȦÀÁǾǎ

Ü(ǴÁÂƐŸƱqǎ ǴĦǴÛǎ Ž 30 ǴĦȦÔǎ Û5 ƵŸǑǎ) "Test for bacterial endotoxins ǴƐηɀǪÀƨǎ ğȦǪȦÀÁǾǎ ǬǅžǰǑ ǿȦǴǪǹɓǎ"
.ƙŸÊǣ ǬÁÂøǴǎ ϕη ŊŸη 1 Ȫõ Ž RS ƟŸǹǎǼǎ ȷÀÀÁǾǎ ϕη ǴƐõȿǻ ǵǼǵȿ 0.01 ϕη ÀǮõǓ Ƀɀȝ ɓ

!ĭƽyǁǫ üƑǅžyƚƨǘǁ ƃyƞǅžǁǫ ǅžĭƙƐɌøǽǴǁǫ ǅžĭǂƨǽǴ üĭɌøǽǴ üǕǓ Ĭʒƒƈǟ ƒǂƯƗǅž

Additional requirements for Benzathin benzylpenicillin for Sterile use

Test for Sterility of non- ϕȪĦŸõ ǴŸǎȦǬǎ Ƙȡ ğǎÀȒĦǪÊƫǎ ǴηȦǬȝ ǬǅžǰǑ ǿȦǴǪǹɓǎ" ȷǎɀȝ ǨƠ ǻǿȿ Ȧƫ ƵƐǅžǪÊÁ
.(ǴÁÂƐŸƱqǎ ǴĦǴÛǎ Ž 32 ǴĦȦÔǎ Û5 ƵŸǑǎ) "injectable preparations

ø ø ø ø ø

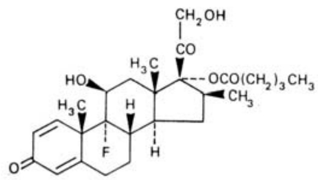
BETAMETHASONI VALERAS

Betamethason Valerate ǅžǋǈƦƙĭǅžƑƗĭǴǁǫ ǀƐƥĭǁƑʒ

$C_{27}H_{37}FO_6$:**Molecular formula** ǴƐȦÁÂƨǎ ǴȣƐÔǎ

476.6 :**Relative molecular mass** ǴƐǴÊǴǎ ǴƐȦÁÂƨǎ ǴŸǪȮǎ

:**Graphic formula** ǦǁǫǼǦţǞ Ǧ8ǁÔöǞ



:**Chemical name** ǓǝǼǁŁǁÒöǞ ǇèɟǞ

9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate; 9-fluoro-11β,21-dihydroxy-16β-methyl-17-[(1-oxopentyl)oxyl]pregna-1,4-diene-3,20-dione; CAS Reg. No. 2152-44-5.

.ǦǶǝǞÀöǞ ƇǼȝ ǕǓǯÀõ ȐǁǞǕ БǕ ȐǁǞǕ ȷǯǕǞ ȧǯǶÊƞ :**Description** Ƶòǯ öǞ

ȷǯǁèɉǞ Ž ȷǞǟşØöǞ Àǵ ǕTS (ȯ/ȟ 750~) ȯǯǫǮǀɋǞ Ž ǡǞşǣ ǕǁǁǕŁȝ ǒǞţǞ Ž ǡǞşǣ Ƙȡ :**Solubility** ǦǁǫǞǟşØöǞ
.R ȳøǯǯşøǯǕÒöǞş R

.Antiinflammatory ǡǞǮǪǑǞ ǻǞȒƞ ǒǞşǻ :**Category** ǦǞǞöǞ

.ǒǯȒöǞ ȸƞ ǦǁŁȚ ǕǮǞÒǵǘǣ ǦǑǕ8ƞ ǦǀşǞǵ Ž ȷşàǞǮǁƞǞǪǁǦöǞ ǧǞƘǒǞǯ ȘǞǵ Ǽƶ :**Storage** ǭȸǀÂǺǪöǞ

REQUIREMENTS ƘǦǕȢƱƘďž!ƒ

ȸȝ ǼǀÂǀ ɟş %96.0 ȸȝ ȌǾǀ ɟǞƞ ȝǕȝ ȷşàǞǮǁƞǞǪǁǦöǞ ǧǞƘǒǞǯ ɃǯǪƠ :**General requirement** ȳǞǶöǞ ǼǕǛǪţǞ
.ǦǞǞÖǞ ǥǻǞţǞ БǕ ţǯǅǞöǞǣ ǦǣǯÊȚ ǕC$_{27}$H$_{37}$FO$_{6}$ ȸƞ %104.0

:**Identification tests** ƕǏǊǋǉǁǫ ǀ ǫƥǦǂǖǫ

.Eş Cş D ǧǞǿǞǦǪǹɟǞ şǕ Bş A ȷǞǿǞǦǪǹɟǞ ĘǦǛǀ ȷǕ ȸǑǯ •

ǒǞǮŁΣǞ ǨƠ ǦȞǐɉǞ ǦǾǛǀƞ Ž ǓǝǯȒöǞ ƵǁǛöǞ ǡǞǼǫ" ȷǞǯǀȝ ǨƠ 8ǯòǯƞ ǯȽǞƞ ǼȆǦ ǑǶǞöǞ ĘǦǛǀ :A
ǨƠ ǦȞǐɉǞ Ž ȋǞÔǪƞɟǞ ƵǁùĘǞǞǛǪǀ .(43 ǦǶǞÔöǞ Ǖ1 ǼǕǑǞ) "Spectrophotometry in the infrared region
ǧǞƘǒǞǞǑ *reference spectrum* ǓǨǅǞţǞ ƵǁǛöǞ ȝƞ şǕ RS ȷşàǞǮǁƞǞǪǁǦöǞ ǧǞƘǒǞǯ ȸƞ ǰǨǞöǞ ƵǁǛöǞ ȝƞ ǒǞǞŁΣǞ
.ȷşàǞǮǁƞǞǪǦöǞ

БǕ 8ǞȒǀ .ȼÊǞǫ ǼǀØţǞǣ Ōƞ 20 БǕ Ōƞ 2 ƵǞǺşTS (ȯ/ȟ750~) ȯǯǫǮǀɋǞ ȸƞ Ōƞ 20 Ž ƞǕƞ 20 ǡǞØǀ :B
Ȑƥ/ȸǀàǞǿǼȽ ŌǁǼǯ ȯǯǕȚ ȸƞ Ōƞ 10 ǿǞǼŌƞ ǥǻǞǼè Ƀǣ ǿǞǦǪǹǞ ǡǯǦǕ Ž ţǯȑǯţǞ ȯǯǕɉǞ ǞØȽ ȸƞ Ōƞ 2
ȸƞ ȠȋǞŁǪöǞ ȷǯÒǀ ɟ .ǼǿǯǯǻǝǀşǕǦŌǁǫǻ 20 ǥǼƞ ◦ȳ 60 ǥǿǞǞǵǦǅǿǼǣ ǓǝǞƞ ȳǞƥ Ž ȸǺÊǀǕǯǞǯ ǕTS ȌǀǿǯǞǕÊöǞ
.0.25 ȸƞ ǞǯõǕ 423 nm ǦǣǞǫ ǓŁȚȝǕ ǦǅǯƞȯǯùǼȝ Ǉè 1 ǦǫǞǺǯǣ ǦǾǦù ȯǕǹ

ǦƐÊƐǝÀöä 3ÕǤöä ĘæÀÛǪǩ ."Related steroids ǦŏÀÎţä ğäÆļşÀǪƐÊöä" ȷäzƘ3 ǨƠ 8ζòζţä øÀǤǪǹғä БÜ ÀŢφä :C

ȸŋ ǦƟÀÀöä ǦƐÊƐǝÀöä ǦȞÕǤöä ĘæÀÛǪǩ ÛÕöØö ǦzÀȓÜ .B ȯζŸǂä ȸŋ ǦƟÀÀöä ÕŸǩ 3ŋ 3ȩζţä Ž CŞ A ƙȯζŸǂä ȸŋ ǦƟÀÀöä

.B ȯζŸǂä ȸŋ ǦƟÀÀöä ÕŸǩ 3ŋ gÆÎöäş ÀƮŢţä Ž A ȯζŸǂä

Û1 ÆŸÕä) "Oxygen flask method ƙDzÊÕǰä ǦŸDZζǵ ǦÕÀÀü" ȷäzƘ3 ǨƠ 8ζòζţä ȧäÀǪǵғä ĘǤÛÀ :D

0.01) ÿζÀåζÔöä ÆƐÊÕşøÆƐȽ ȯζŸȚ ȸŋ Ōŋ 0.5 ȸŋ ǰÀÂŋş øÀǤǪǹғä gåÀŋ ȸŋ ŋŸŋ 7 ÿäÆǺǪèÀæ Û(132 ǦĦÀÔöä

Ōŋ 0.1 ȸŋ ǰÀÂŋ ȸŋ Ōŋ 0.1 8ÀȒÀ ÛǦƐŸȶĦöä ŌȶǪȮǩ ÀŋÆƘ3 .absorbing îÀǪ ŌǝÀÊÕ öÀţä Ōŋ 20ş VS (ȯ/ȯζŋ

ÜZirconyl nitrate TS ȯζŸȚ ȸŋ Ōŋ 0.1ş ÀDZäÀù ÀȒȚ TS (ȯ/ȟ1) Sodium alizarin sulfonate ȯζŸȚ ȸŋ

.ÀÀòǰä ȷζŸöä БÜ Àþǰä ȯζŸǂä ȷζö ȯÆǤǪÀ

ÛåƎÀ .ĘǝÀȩå 5 gÆŋ ɄǝÀŋ ÿÀþ Ž TS1 ȯζφÀǯÀǭä/ÿζƐèÀǩζǤöä ÆƐÊÕşøÆƐȽ ȯζŸȚ ȸŋ Ōŋ 2.0 3ŋ 0.05 ȸǺÊƚ :E

ŌƐǯÀǭä ğäǨöÀζ ǦĦǝäø ĘŸÛÀǩ ÜǦÕƐȩå 1 gÆţ ƵÛŸæ ɁŸ8Àş ÛTS (ȯ/ȟ100~) ÕÀøζÀŸÊöä ȒÞ ȸŋ Ōŋ 2.0 8ÀȒÀş

.ɭÎöÀæ ȭäøåȒö ǦŸæÀÕöä/ǦÀƐÛŸöä

ÜȷÀÊÕζÀÆöä Ž Ōŋ/ŋŸŋ 10 ÂƐÕÀǪæ ȯζŸȚ ÿÆǺǪÊÀ :Specific optical rotation Ʉ3ζÀöä ɃÀÔǤöä ÀÀşÆǪöä

.$[a]_{\mathrm{D}}^{20^{\circ}\mathrm{C}} = +75 \text{ to} + 81^{\circ}$

.ȟ/ŋŸŋ 2.0 ȸ3 ÆÀÂÀ ғ ÜƙǨƳǤöä ȸŋ ǦÕǩζæ Ž (ȧÀĦƚ) ÆŋÀƚş ȟ0.1 ȷàζÀ :Sulfated ash ǨÀŸÊţä åÀŋÀöä

.ȟ/ŋŸŋ 5.0 ȸŋ ÀǯÕÜ ÆÕÀÀ ғ Ü°ÿ 105 ǦDZøÆöÀæ ǨæÀǯöä ȷàζöä ɁøǪǵ ƵÀƶ :Loss on drying ƵƐÀDZǪöÀæ ÆÕÀöä

Thin- ǦÕƐȩÀöä ǦÕǤÛöä ȃäÀÎǪèä" ȷäzƘ3 ǨƠ 8ζòζţä øÀǤǪǹғä ĘǤÛƚ :Related steroids ǦŏÀÎţä ğäÆļşƘǪÊöä

ȸŋ ǰÀÂŋş ǦŸɸ8ŋ gåÀȶÕ Silica gel R1 ÀÖƐŸƐÊöä ǦŋƳȽ ÿäÆǺǪèÀæ Û(84 ǦĦÀÔöä Û1 ÆŸÕä) "layer chromatography

ŸÔÀÀŋ ĘǤÛÀ .ȭÀĦǪŋ øζÛÕ öÀţä ȸŋ ÀȶDzǵ 0.2ş ÛR ȯζφÀǯƐţä ȸŋ ÿζDzǵ 5 ÛR ȷÀǯÀÜ øζŸÕ ɄǝÀǪ ȸŋ ÀȶDzǵ 95

ȯζŸǂä ÛR ȯζφÀǯƐţä ȸŋ ÀȶDzǵ 1ş R ÿøζζşøζŸÕ ÿζDzǵ 9 ȸŋ ǰÀÂŋ Ž ƙÀǪä ƙȯζŸȚ ȸŋ ÀǪöş ÀÖŋ 1 ǦĦƐÀÔöä ɁŸ3

ÕÕ Ž RS ȷşàÀǯƐŋÀǪƐǤöä ğäǨöÀζ ȸŋ ŋŸŋ 15 Ƀζ3 :(B) ȯζŸǂäş Ōŋ 1 ÕÕ Ž øÀǤǪǹғä gåÀŋ ȸŋ ŋŸŋ 15 Ƀζ3 :(A)

A ȯζŸǂä ȸŋ ƙöåÀĦǪŋ ƙȶDzǵ ǰÀÂŋ ȸŋ ȷζŌŋ (C) ǬöÀǪ ȯζŸȚ ȸŋ ÀǪöş ÀÖŋ 2 ǦĦƐÀÔöä ɁŸ3 ÀȒÀÜ ĘǤÛÀ ÜŌŋ 1

¢ÊÀφ ÆÀØţä ȸŋ Ōŋ 1 ÕÕ Ž øÀǤǪǹғä gåÀŋ ȸŋ ŋŸŋ 0.15 ɁŸ3 ɃζǪ3 (D) 3ääø ȯζŸȚ ȸŋ ÀǪöşÀÖŋ 1ş Bş

ÀǺǤǪǩ ɁøǪǵ öäζTä Ž ƵDzǪö ȭÀǪǩ ÛȃäÀÎǪèғä gKDzǵ ȸŋ ǦĦƐÀÔöä ţÂφ ÆĦæş .Bş A ƙȯζŸĦȶŸö ÿÆǺǪÊţä

ÆƐÊÕşøÆƐȽ/ÿζƐöşàäÀǪǪöä ǦȩøàÀ ȯζŸĦŋ æÀÀş ÛåƎǪö ȭÀǪǩş ÛĘǝÀȩå 10 gÆŋ °ÿ 105 ǦDZøÆöÀæ ǦĦƐÀÔöä ȸǺÊƚ Ż .ğÀǤÀØţä

ǦȞÕǤöä öÀǯǪèÀæ ÛA ȯζŸǂä ȸŋ ǰǪÀǩ ǦȞÕæ ǦÀÜ ȷζÖǩ ғ .øÀƮÀöä öζȓ Ž ȃäÀÎǪèғä ÙÛÙ ÒĦÀƚş ÛTS ÿζÀåζÔöä

.D ȯζŸǂä ȸŋ ǦƟÀÀöä ÕŸǩ ȸŋ gÆì ÀǯÕÜ ÛǦƐÊƐǝÀöä

[illegible] :**Assay**

- [illegible].

[illegible] TS (ò/ȟ750~) [illegible] 20 [illegible] TS (ò/ȟ750~) [illegible] 20 [illegible] 100 [illegible] 25 [illegible] 10.0 [illegible] 100 [illegible] R. [illegible] TS [illegible] 2.0 [illegible] TS [illegible] 0.2 [illegible] 1 [illegible] R. [illegible] TS (ò/ȟ750~) [illegible] 30 [illegible] 525 [illegible] 1 [illegible] 25 [illegible] (ò/ȟ750~) [illegible] 10 [illegible] RS [illegible] $C_{27}H_{37}FO_6$ [illegible].

ØØØØØ

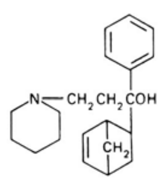
BIPERIDENUM

Biperiden البيبريدين

[illegible] :**Molecular formula** $C_{21}H_{29}NO$

[illegible] :**Relative molecular mass** 311.5

[illegible] :**Graphic formula**



[illegible] :**Chemical name**

α-5-Norbornen-2-yl-α-phenyl-1-piperidinepropanol; α-bicyclo[2.2.1]hept-5-en-2-yl-α-phenyl-1-piperidinepropanol; CAS Reg. No. 514-65-8.

[illegible] **Description** [illegible]

[illegible] **Solubility** [illegible]
.TS (750~) [illegible]

[illegible] **Category** [illegible] .Antiparkinsonism

[illegible] **Storage** [illegible]

REQUIREMENTS [illegible]

[illegible] **General requirement** [illegible] %98.0 [illegible] %101.0 [illegible]
$C_{21}H_{29}NO$ [illegible]

Identification tests [illegible]:

• [illegible] A [illegible] .DS CS B [illegible]
A: [illegible]
"Spectrophotometry in the infrared region (43 [illegible] 1 [illegible]) [illegible]
[illegible] RS [illegible] *reference spectrum* [illegible]
B: [illegible] 20 [illegible] 5 [illegible] TS (1440~) [illegible]
C: [illegible] 0.20 [illegible] 80 [illegible] 0.5 [illegible] TS (70~) [illegible]
[illegible] 5 [illegible] bromine TS1 [illegible]
[illegible] TS1 [illegible]
D: [illegible] 114 °[illegible]

[illegible] **Sulfated ash** [illegible] 1.0 [illegible]

[illegible] **Loss on drying** [illegible] 105 °[illegible] 10 [illegible]

[illegible] **Related substances** [illegible] Thin-
"layer chromatography (84 [illegible] 1 [illegible]) [illegible] Silica gel R1
[illegible] (0.5 [illegible]) VS [illegible] 96.5 [illegible] Toluene
R 3.5 [illegible] 5 [illegible]
(A): [illegible] 40 [illegible] 1 [illegible] (B): [illegible] 0.20 [illegible] 1 [illegible].

Potassium idobismuthate TS2 ... B.

0.15 ... R1 ... 30 ... 0.4 ... **Assay** ...
VS (0.1) ... 1-naphtholbenzein/acetic acid TS ...
A ... "Non-aqueous titration" ... (142 ... 1 ... VS (0.1) ... 31.5 ... $C_{21}H_{29}NO$.

Additional requirement for Biperiden for parenteral use

"*Parenteral preparations*" ... (56 ... 4) ...

ø ø ø ø ø

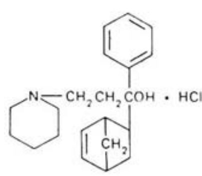
BIPERIDENI HYDROCHLORIDUM

Biperiden hydrochloride

Molecular formula: $C_{21}H_{29}NO,HCl$

Relative molecular mass: 347.9

Graphic formula:



Chemical name:

α-5-Norbornen-2-yl-α-phenyl-1-piperidinepropanol hydrochloride; α-bicyclo[2.2.1]hept-5-en-2-yl-α-phenyl-1-piperidinepropanol hydrochloride; CAS Reg. No. 1235-82-1.

Description: ...

Solubility: ... R ... (750~) TS ... R.

.Antiparkinsonism ǦǆǍǕǺǾǚǞ ǻǖǞǬ ǒǟǤ ǻ :**Category** ǦǞǞǒǟ

.ǒǍǞǒǟ ǳ ǦǆǢ ǛǶǞǑǵǙ ǦǑǴǬ ǦǞǤǞǵ Ž ǳǄǆǞǨǆǦǒǟ ǺǞǔǍǨǑǤǔǺǄǆ ǨǞǵ ǻǬ :**Storage** ǳǞǠǞǠǒǟ

REQUIREMENTS ǨǦǻǬǑǾǭǃƒ

ǳ3 ǺǞǠǞ ǃǤ %98.0 ǳ3 ǑǑǞ ǃǞǬ ǜǞ3 ǳǄǆǞǨǆǦǒǟ ǺǞǔǍǨǑǤǔǺǄǆ ǨǍǞ3 :**General requirement** ǶǞǨǒǟ ǼǞǛǞǖǟ
.ǦǞǞǑǟ ǵǞǖǟ Ǯǻ ǖǍǜǞǒǞǟ ǦǍǊǥ ǛC$_{21}$H$_{29}$NO,HCl ǳǬ %101.0

:**Identification tests** ǚǍǉǊǏ ǐǳǲǦǏ

.D ǤC ǤB ǵǟǺǞǠǞǃǟ ǤǛ D ǤA ǳǞǺǞǠǞǃǟ ǣǦǛǞ Ǆǻ ǳǑǍ •

ǒǟǞǆΣǟ ǨǑ ǦǞǞǃǟ ǦǑǛǞǬ Ž ǇǍǒǟ ǍǛǟ ǟǞǨ" ǄǟǍǞ3 ǨǑ 8ǍǒǍǬ ǍǞǬ ǼǞǕ ǺǞǠǞǃǟ ǣǦǛǞ A
ǨǑ ǦǞǞǃǟ Ž ǞǞǑǬǃǟ ǍǞǙ ǣǟǞǛǞ .(43 ǦǚǞǑǒǟ Ǜ1 ǼǞǑǟ) "Spectrophotometry in the infrared region
reference spectrum ǙǨǍǞǖǟ ǍǛǟ 3ǬǤǛ RS ǳǄǆǞǨǆǦǒǟ ǺǞǔǍǨǑǤǔǺǄǆ ǳǬ ǚǞǞǒǟ ǍǛǟ 3Ǭ ǒǟǞǆΣǟ
.ǳǄǆǞǨǆǦǒǟ ǺǞǔǍǨǑǤǔǺǄǆ

.ǞǬǛ ǄǍǑ ǚǞ ǛǺǟǞǑǞǞǑǛ ǑǞǞǤ TS (ǒ/ǚ 1440~) ǑǞǺǍǞǞǕǒǟ ǨǷ ǳǬ ǑǬ 5 Ž ǫǟǬ 20 ǟǟǺǞ B
ǛǵǞǛǑǍ ǵǞǛǤ bromine TS1 ǶǤǟǒǟ ǒǍǜǞ ǳǬ ǒǍǜǞǃǟ ǟǺǞ ǳǬ ǑǬ 5 Ǯǻ 8ǞǬǤ ǒǞǬ ǑǬ 50 Ž ǚ0.10 ǟǟǺǞ C
.ǦǍǺǞǕǬ ǦǟǞǒǟ ǚǞǞ TS1 ǶǤǟǒǟ ǒǍǜǞ ǳǬ ǵǞǞǟ ǦǍǞǞǛ ǺǞ3ǤǤ .ǑǞǞǚǞǬ ǺǞ3 ǟǤǺǞ ǄǍǜǞǒǟ ǒǟǞǒ ǦǟǞǒǟ ǚǞǞ
General ǦǬǞǒǟ 8ǟǞǞǒǃǟ ǵǟǺǞǠǞǃǟ" ǄǟǍǞ3 ǨǑ 8ǍǒǍǖǟ ǮǑ3ǞǞǒǟ ǑǬ/ǫǟǬ20 ǞǆǑǞǞǟ ǒǍǜǞǃǟ ǙǛǞǞ D
.(121 ǦǚǞǑǒǟ Ǜ1 ǼǞǑǟ) chlorides ǵǟǺǞǍǜǑǟ ǞǆǬ Ǒ3ǞǞǑ"identification tests

.ǚ/ǫǟǬ 1.0 ǳ3 ǺǞǠǞ ǃ :**Sulfated ash** ǨǞǜǕǖǟ ǻǞǬǞǒǟ

.ǚ/ǫǟǬ 5 ǳǬ ǞǑǛ ǺǑǞǞ ǃ Ǜ°ǜ 105 ǦǍǺǺǟ ǵǞ3ǞǞ 3 ǵǺǖ ǍǞǵ :**Loss on drying** ǍǞǍǞǞǟ ǺǑǞǒǟ

ǦǑǞǒǟ ǦǑǛǒǟ ǟǟǞǞǞǞ" ǄǟǍǞ3 ǨǑ 8ǍǒǍǬ ǍǞ ǞǆǑ ǺǞǠǞǃǟ ǣǦǛǞ :**Related substances** ǦǒǞǞǖǟ ǻǟǍǖǟ
Silica ǞǑǞǞǕǒǟ ǦǬǞ ǣǞǞǞǕǬ ǦǕǞǞ ǦǚǞǞǒ ǶǟǺǞǞǞǞ Ǜ(84 ǦǚǞǑǒǟ Ǜ1 ǼǞǑǟ) "Thin-layer chromatography
ǳǍǑǍǞǒǟ ǳǬ ǞǆǍǵ 96.5 ǳǬ ǚǞǞǬ ǑǞǚǞǬ ǺǍǛǑǤ ǛVS (ǒ/ǒǍǬ 0.5) ǶǍǞǻǍǑǒǟ ǺǞǕǑǤǺǄǆ ǒǍǜǞ ǙǺǍ gel R1
:(A) ǒǍǜǞǃǟ ǛR ǒǍǞǞǞǖǟ Ž ǨǞǟ ǨǒǍǜǞ ǳǬ ǞǞǤ ǞǑǬ 10 ǦǚǞǑǒǟ ǜǞ3 ǦǑǞǞǬ ǣǦǛǞ .R ǒǍǞǞǞǖǟ ǳǬ ǞǆǍǵ 3.5Ǥ
ǖǞ ǼǞǤ .ǑǬ 1 ǑǑ Ž ǺǞǠǞǃǟ ǵǞǬ ǳǬ ǫǟǬ 0.10 ǨǍ3 :(B) ǒǍǜǞǃǟǤ ǑǬ 1 ǑǑ Ž ǺǞǠǞǃǟ ǵǞǬ ǳǬ ǫǟǬ 20 ǨǍ3
ǛǛǛ ǑǚǞǤ Ǜpotassium iodobismuthate TS2 ǒǍǚǬ ǻǞǤ ǛǒǍǞǟ Ž ǍǍǑ ǑǞǞ ǛǵǨǍǵ ǳǬ ǦǚǞǑǒǟ
ǦǟǞǒǟ ǑǞǞ ǳǬ ǵǺǞ ǞǑǛ ǛǦǕǞǒǟ ǦǞǑǒǟ ǒǞǑǞǟ ǛA ǒǍǜǞǃǟ ǳǬ ǚǞǞ ǦǞǞ ǦǛ ǄǍǑ ǃ .ǺǞǆǒǟ ǒǍǷ Ž ǟǟǞǞǞǞǃǟ
.B ǒǍǜǞǃǟ ǳǬ

ǍǛǟ ǳǞǕǤ ǛR1 ǙǍǞǒǟ ǑǞǞǃǟ ǨǷ ǳǬ ǑǬ 30 Ž ǛǦǞǍǬ ǦǤǟǍǬ Ǜǚ0.4 ǟǟǺǞ :**Assay** ǦǕǞǑǖǟ
:ǞǞǞǖǟ ǒǍǜǞ ǳǬ ǑǬ 0.15Ǥ TS ǑǞǞǃǟ ǨǷ/ǣǞǒǟ ǵǞǞǛ ǒǍǜǞ ǳǬ ǑǬ 10 8ǞǬǤ ǛǒǍǜǞǃǟ ǜǞ3 ǒǍǑǚǞ

ǨƠ ȸǫǒǫ ǫȽǠ ǼÊШÛVS (ȯ/ȯǫ 0.1) ǬǢǿǫỶǬşǨ ȐȾШ ÀǠǺǠ .1-naphtholbenzein/acetic acid TS ǬǢ 1 ǬǬ .(142 ǦǶǠÔ Û1 ǼỶǑ) A ǦǬǠÀÛ ǼÊШ Û"Non-aqueous titration ȾǝǠȠƳ Ǜèǫ Ž ǥÀǠǨţ" ȷǟǫǠȝ

.$C_{21}H_{29}NO,HCl$ ȸȠ ȠỶȠ 34.79 ǜǫǠȮǠ VS (ȯ/ȯǫ 0.1) ǬǢǿǫỶǬǨ Ȑ ƥ ȸȠ

ø ø ø ø ø

BLEOMYCINI HYDROCHLORIDUM

Bleomycin hydrochloride ǄǏ ƨǏǄǊǏǤ ƣǏƥǊǂ ǋƥƣǏǉ

(**non-injectable** ǄȿƟǂ üǤȿǁ ƥǏȜ) ǄǏ ƨǏǄǊǏǤ ƣǏƥǊǂ ǋƥƣǏǉ

Sterile !ǏȿƴǁÛǄǏ ƨǏǄǊǏǤ ƣǏƥǊǂ ǋƥƣǏǉ

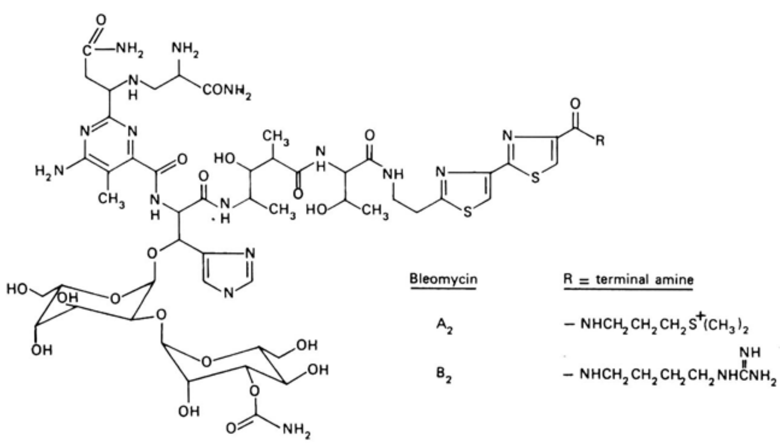
ǦǂÊỶÊǪţ ǫƴ Ǝȝ ǰǪǨ ǻǟǫ ǰǠÂţ ɃǼǿǫỶǬşǿǼǮT ǴỶţ ǫȽ ƙÊǭǫǮỶ ǼǠǿǫỶǬşǿǼǮȽ :**Composition** ǼǮǬÀǪ CAS Reg. ÜB$_2$ ƙÊǭǫǮỶş A$_2$ ƙÊǭǫǮỶ ǠƵ ǰǠÂȾỶ ȷǠǮÊǮǝÀ ȷǠǫǫȮţ .*Streptomyces verticillus* ǦǭǟşǼ .No. 67763-87-5

.$C_{55}H_{84}N_{17}O_{21}S_3,Cl$:A$_2$ ƙÊǭǫǮỶ ǼǠǿǫỶǬşǿǼǮȽ :**Molecular formula** ǦǮǠǠÂƨ Ǧ8ǮÔ

.$C_{55}H_{84}N_{20}O_{21}S_2,HCl$:B$_2$ ƙÊǭǫǮỶ ǼǠǿǫỶǬşǿǼǮȽ

ǼǠǿǫỶǬşǿǼǮȽ Ü1452 :A$_2$ ƙÊǭǫǮỶ ǼǠǿǫỶǬşǿǼǮȽ :**Relative molecular mass** ǦǮǤÊǠ ǦǮǠǠÂƨ ǦỶǪȮ 1461 :B$_2$ ƙÊǭǫǮỶ

:**A$_2$/B$_2$ bases** ƙèǠèɉ **B$_2$/A$_2$** ƙÊǭǫǮỶỶ ǦǮǠǮǤţ Ǧ8ǮÔ



[illegible] **Chemical name**:

Bleomycin A_2 hydrochloride: N^1-[3-(Dimethylsulfonio)-propyl]bleomycinamide chloride; [3-[2′-[2-[(2*S*,3*R*)-2-[(2*S*,3*S*,4*R*)-4-[(2*S*,3*R*)-2-[6-amino-2-[(1*S*)-1-[[(2*S*)-2-amino-2-carbamoylethyl]amino]-2-carbamoylethyl]-5-methyl-4-pyrimidinecarboxamido]-3-[[2-*O*-(3-*O*-carbamoyl-α-D-mannopyranosyl)-α-L-gulopyranosyl]oxy]-3-imidazol-4-ylpropionamido]-3-hydroxy-2-methylvaleramido]-3-hydroxybutyramido]ethyl][2,4′-bithiazole]-4-carboxamido]propyl]dimethylsulfonium chloride; CAS Reg. No. 49830-49-1.

Bleomycin B_2 hydrochloride: N^1-(Guanidinobutyl)bleomycinamide hydrochloride; (β*S*)-4-amino-β-[[(2*S*)-2-amino-2-carbamoylethyl]amino]-6-[[(1*S*,2*R*)-2-[[2-*O*-(3-*O*-carbamoyl-α-D-mannopyranosyl)-α-L-gulopyranosyl]oxy]-1-[[(1*R*,2*S*,3*S*)-3-[[(1*S*,2*R*)-1-[[2-[4-[(4-guanidinobutyl)carbamoyl][2,4′-bithiazol]-2′-yl]ethyl]carbamoyl]-2-hydroxypropyl]carbamoyl]-2-hydroxy-1-methylbutyl]carbamoyl]-2-imidazol-4-ylethyl]carbamoyl]-5-methyl-2-pyrimidinepropionamide hydrochloride; N^1-[4-[(aminoiminomethyl)amino]butyl]bleomycinamide hydrochloride; CAS Reg. No. 55658-44-1.

[illegible] **Description**: [illegible].

[illegible] **Solubility**: [illegible] (750~) [illegible]

Category: [illegible] Cytotoxic.

Storage: [illegible].

Labelling: [illegible]

[illegible]

[illegible]

REQUIREMENTS [illegible]

General requirement: [illegible] 1500 [illegible] 2000 [illegible] B_2/A_2 [illegible] 1 [illegible]

[illegible] 55.0% [illegible]

[illegible] 70.0% [illegible] A_2 [illegible] 25.0% [illegible] 32.0% [illegible] B_2 [illegible]

[illegible] A_2 [illegible] B_2 [illegible] 85% [illegible] A_5 [illegible] 7.0%

B4 %1.0 ... A2 ... demethylbleomycin ... %3.0.

Identification tests:

A ... 5 ... 10 ... 5 ... (II) (160/...) TS
290 ... 268 ... 100 ... 242 ...

B ... 10 ... B ... General
identification tests" ... chlorides (121 ...).

Loss on drying: ... 60 °... 0.6 ...
5 ... 4 ... 60 .../...

pH value: ... 5.0 ... 4.5 - 6.0.

Copper content: ... 75 ... 60 ... 10
(0.1 .../...) TS. 10 ... TS2 ...
... Zin bis (dibenzyldithiocarbamate)TS ... 10 ... 1 ...
... R ... 1 ...
... 435 ...
R ...

... (*Ao*X15)/(*As*X*W*) ... *Ao* ...
As ... TS2 ... *W* ...
0.2 .../...

Assay:

A ... *Microbiological assay* ...
"Microbiological assay of antibiotics" (155 ... 1 ...)
(ATCC 607) *Mycobacterium smegmatis* ... inoculum ...
... 48-40 ... 27 °... Cm8.
... 3 ... Saline TS ... 100 ...
Cm9 50 ... 27-25 °... 5 ...

[illegible] 14 [illegible] .orbital shaker [illegible]
[illegible] 0.5 [illegible] inoculated plates [illegible] .°[illegible] 5 [illegible]
[illegible] .°[illegible] 27 [illegible] Cm8 [illegible]
International [illegible] TS [illegible]7.0 [illegible] reference solution
.([illegible] 1 [illegible] 200[illegible] 10 [illegible]) [illegible] B_2/A_2 [illegible] Reference Preparation
[illegible] estimated potency (*P*= 0.95) [illegible]
[illegible] (*P*= 0.95) [illegible] %105 [illegible] %95
1 [illegible] B_2/A_2 [illegible] 2000 [illegible] 1500 [illegible]
.[illegible]

[illegible] A [illegible] .*Content of the bleomycin components* [illegible] :B
.packing material [illegible]

[illegible] 1 [illegible] [1]377-373 [illegible]
25 [illegible] "High performance liquid chromatography [illegible]"
[illegible] 10-5 [illegible] 4.6 [illegible]
linear [illegible] .octadecyl silyl groups [illegible]
[illegible] 1-pentanesulfonic acid TS [illegible] 9 [illegible] gradient development
1-pentane sulfonic acid TS [illegible] 6 [illegible]
[illegible] 4[illegible]
[illegible]1.86 :[illegible] 60 [illegible]
[illegible] detector [illegible] .([illegible]1 [illegible] R [illegible]
5 [illegible] .([illegible] 20-8) [illegible] 254 [illegible]
[illegible] .[illegible] 1 [illegible] 5 [illegible]
[illegible] gradient elution [illegible]
.[illegible] A_2 [illegible] 80

[illegible] bleomycin acid [illegible] void [illegible]
.[illegible] A_2 [illegible] B_4 [illegible] A_5 [illegible] B_2 [illegible] A_2 [illegible]

.([illegible]) [illegible] [1]

[illegible] areas [illegible] peaks [illegible].

[illegible]

Additional Requirements for Sterile Bleomycin Hydrochloride

[illegible] **:Storage** [illegible]

[illegible] **:Histamine-like substances** [illegible] (167 [illegible] 1 [illegible]) "Test for histamine-like substances [illegible] 500 [illegible] TS [illegible] 1 [illegible].

Sterility testing of [illegible] **:Sterility** [illegible] (162 [illegible] 1 [illegible]) "antibiotics [illegible].

[illegible]

Additional requirements for Bleomycin hydrochloride for Sterile use

Test for Sterility of non- [illegible] (32 [illegible] 5 [illegible]) "injectable preparations [illegible].

[illegible] **:Bacterial endotoxins** [illegible] (30 [illegible] 5 [illegible]) "Test for bacterial endotoxins [illegible] 10.0 [illegible] RS [illegible] 1 [illegible].

ØØØØØ

BLEOMYCINI SULFAS

Bleomycin sulfate [illegible]

(**non-injectable** [illegible])

Sterile [illegible]

[illegible] **:Composition** [illegible] *Streptomyces verticillus*. [illegible] A_2 [illegible] B_2: CAS Reg. No. 9041-93-4.

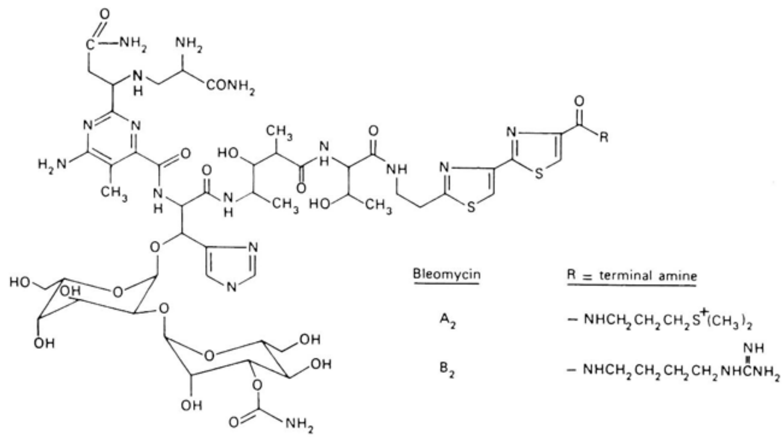
ƙÊĦƞƺĚƳǴöä ğĪÄŸè Ü$C_{55}H_{84}N_{17}O_{21}S_3,HSO_4$:A2 ƙÊĦƞƺĚƳǴöä ğĪÄŸè :**Molecular formula** ǴĦĪÄÂƨä Ǵ8ĦÔöä

.$C_{55}H_{84}N_{20}O_{21}S_2,HCl$:B_2

:B_2 ƙÊĦƞƺĚƳǴöä ğĪÄŸè Ü1514 :A_2 ƙÊĦƞƺĚƳǴöä ğĪÄŸè :**Relative molecular mass** ǴĦǴÊĀöä ǴĦĪÄÂƨä ǴŸǪÒöä

.1524

:**A_2/B_2 bases** ƙèĪèɟä **B_2/A_2** ƙÊĦƞƺĚƳŸö ǴĦφĪĦǴţä Ǵ8ĦÔöä



:**Chemical name** ƟəĪĦŧĦÒöä ʅèŧä

Bleomycin A_2 sulfate: N^1-[3-(Dimethylsulfonio)propyl]bleomycinamide hydrogen sulfate; [3-[2′-[2-[(2*S*,3*R*)-2-[(2*S*,3*S*,4*R*)-4-[(2*S*,3*R*)-2-[6-amino-2-[(1*S*)-1-[[(2*S*)-2-amino-2-carbamoylethyl]amino]-2-carbamoylethyl]-5-methyl-4-pyrimidinecarboxamido]-3-[[2-*O*-(3-*O*-carbamoyl-α-D-mannopyranosyl)-α-L-gulopyranosyl]oxy]-3-imidazol-4-ylpropionamido]-3-hydroxy-2-methylvaleramido]-3-hydroxybutyramido]ethyl][2,4′-bithiazole]-4-carboxamido]propyl]dimethylsulfonium hydrogen sulfate.

Bleomycin B_2 sulfate: N^1-(Guanidinobutyl)bleomycinamide; (β*S*)-4-amino-β-[[(2*S*)-2-amino-2-carbamoylethyl]amino]-6-[[(1*S*,2*R*)-2-[[2-*O*-(3-*O*-carbamoyl-α-D-mannopyranosyl)-α-L-gulopyranosyl]oxy]-1-[[(1*R*,2*S*,3*S*)-3-[[(1*S*,2*R*)-1-[[2-[4-[(4-guanidinobutyl)carbamoyl][2,4′-bithiazol]-2′-yl]ethyl]carbamoyl]-2-hydroxypropyl]carbamoyl]-2-hydroxy-1-methylbutyl]carbamoyl]-2-imidazol-4-ylethyl]carbamoyl]-5-methyl-2-pyrimidinepropionamide sulfate (salt); N^1-[4-[(amino-iminomethyl)amino]butyl]bleomycinamide sulfate (salt).

.ƟƺĪÒöĪǽ ɹƺŸƞ ʂǗ ȐĦǽǗ ɹƺŸǽ ÕÒÎöä ƇƎ ȧƺĦŀÊƞ :**Description** Ȥòƺöä

.ĦǼǄ öĪţä Ž ǟäʂǽ :**Solubility** ǴĦφĪǽʂØöä

.Cytotoxic ĪĦŸǺŸö ƴĪè öäʂǻ :**Category** ǴĪÄöä

[illegible] :**Storage** [illegible].

[illegible] :**Labelling** [illegible]

[illegible]

[illegible]

REQUIREMENTS [illegible]

[illegible] :**General requirement** [illegible] B_2/A_2 [illegible] 2000 [illegible] 1500 [illegible] 1 [illegible]

[illegible] %55.0 [illegible] B_2 [illegible] %32.0 [illegible] %25.0 [illegible] A_2 [illegible] %70.0 [illegible] B_4 [illegible] %7.0 [illegible] A5 [illegible] %85 [illegible] B_2 [illegible] A2 [illegible] .%3.0 [illegible] demethylbleomycin [illegible] A_2 [illegible] %1.0 [illegible]

:**Identification tests** [illegible]

TS (160) (II) [illegible] 5 [illegible] 10 [illegible] 5 [illegible] A [illegible] 100 [illegible] 268 [illegible] 290 [illegible] 242 [illegible]

General [illegible] A [illegible] 10 [illegible] B [illegible] (123 [illegible] 1 [illegible]) "identification tests

[illegible] 0.6 [illegible] 60 [illegible] :**Loss on drying** [illegible] 60 [illegible] 4 [illegible] 5 [illegible]

6.0-4.5 [illegible] 5.0 [illegible] :**pH value** [illegible]

10 [illegible] 60 [illegible] 75 [illegible] :**Copper content** [illegible] TS2 [illegible] 10 [illegible] TS [illegible] 0.1) [illegible] 1 [illegible] Zinc bis (dibenzyldithio carbamate TS [illegible] 10 [illegible] R [illegible] 1 [illegible]

[illegible] 435 [illegible] 1 [illegible] .R [illegible]

[illegible] A_o [illegible] $(A_o \times 15)/(A_s \times W)$ [illegible] W [illegible] TS2 [illegible] A_s [illegible] 0.2 [illegible]

:Assay [illegible]

A [illegible] ***Microbiological assay*** [illegible] "Microbiological assay of antibiotics [illegible] (155 [illegible] 1 [illegible]) [illegible] inoculum [illegible] *Mycobacterium smegmatis* (ATCC 607) [illegible] 50 [illegible] Cm9 [illegible] 27 °[illegible] 48-40 [illegible] Orbital [illegible] 5 [illegible] 27-25° [illegible] .shaker [illegible] 14 [illegible] 5° [illegible] inoculated plaks [illegible] reference Solution [illegible] 27 °[illegible] Cm8 [illegible] International Reference Preparation [illegible] 7.0 [illegible] TS [illegible] B2/A2 [illegible] 10 [illegible] 200 [illegible] 1 [illegible] %95 [illegible] estimated potency (P = 0.95) [illegible] 1500 [illegible] (P = 0.95) [illegible] %105 [illegible] B_2/A_2 [illegible] 2000 [illegible] 1 [illegible]

B: [illegible] *Content of the bleomycin components* [illegible] A [illegible] 377-373 [illegible] .packing material [illegible] "High performance liquid chromatography [illegible] 1 [illegible] 10-5 [illegible] 4.6 [illegible] 25 [illegible] .Octadecyl silyl groups [illegible] 1 1-pentanesulfonic acid TS [illegible] 9 [illegible] linear gradient development [illegible] 1- TS [illegible] 6 [illegible] R [illegible]

[illegible] 4 [illegible] pentanesulfonic acid [illegible] 60 [illegible] detector [illegible] 1 [illegible] R [illegible] 1.86 [illegible] 20-8) [illegible] 254 [illegible] 5 [illegible] 5 [illegible] gradient elution [illegible] 1 [illegible] A2 [illegible] 80 [illegible].

bleomycin acid [illegible] Void [illegible] A_2 [illegible] B_4 [illegible] A_5 [illegible] B_2 [illegible] A_2 [illegible] areas [illegible] peaks.

[illegible]

Additional Requirements for Sterile Bleomycin Sulfate

Storage: [illegible].

Histamine-like substances: [illegible] (167 [illegible] 1 [illegible]) "Test for histamine-like substances [illegible] 500 [illegible] TS [illegible] 1 [illegible] 1 [illegible] 1 [illegible].

Sterility: [illegible] "Sterility testing of [illegible] antibiotics" (162 [illegible] 1 [illegible]) [illegible].

[illegible]

Additional Requirements for Bleomycin Sulfate for Sterile use

Test for Sterility of non- [illegible] injectable preparations" (32 [illegible] 5 [illegible]) [illegible].

Bacterial endotoxins: [illegible] "Test for bacterial endotoxins [illegible] 30 [illegible] 5 [illegible]) [illegible] RS [illegible] 1 [illegible] 10.0 [illegible].

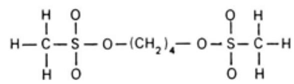
BUSULFANUM

Busulfan [illegible]

$C_6H_{14}O_6S_2$:**Molecular formula** [illegible]

246.3 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

1,4-Butanediol dimethanesulfonate; tetramethylene dimethanesulfonate; CAS Reg. No. 55-98-1.

.Myelosanum [illegible] :**Other name** [illegible]

.[illegible] :**Description** [illegible]

[illegible] :**Solubility** [illegible]
.TS ([illegible]750~)

.Cytotoxic [illegible] :**Category** [illegible]

.[illegible] :**Storage** [illegible]

[illegible] :[illegible] :**Additional information** [illegible]
.[illegible]

REQUIREMENTS [illegible]

[illegible] %100.5 [illegible] %98.5 [illegible] :**General requirement** [illegible]
.[illegible] $C_6H_{14}O_6S_2$

:**Identification tests** [illegible]

[illegible] VS ([illegible] 1) [illegible] 5 [illegible] 10 [illegible] 0.1 [illegible] :A
[illegible] methanesulfonic acid [illegible]
.B [illegible]

[illegible] 0.05 [illegible] A [illegible] :B

[illegible] (ò/ȟ10) TS [illegible] 0.05 [illegible] (ò/ȟ100~) TS [illegible] 2 [illegible] A [illegible]
[illegible] (ò/ȟ10) TS [illegible].

C: [illegible] 0.10 [illegible] 1.0 [illegible] TS 0.5 [illegible] (ò/ȟ260~) TS [illegible] 0.5 [illegible] (ò/ȟ60~) TS [illegible] 1. [illegible] blank [illegible] 2. [illegible] 5 [illegible] (ò/ȟ70~) TS 4.0 [illegible] 1.0 [illegible] (ò/ȟ50) TS [illegible] 2 [illegible] 1 [illegible].

[illegible] **Melting range:** 115-118 [illegible].

[illegible] **Sulfated ash:** [illegible] 1.0 [illegible].

[illegible] **Loss on drying:** [illegible] 60 [illegible] 5 [illegible] 0.6 [illegible] 20 [illegible].

[illegible] **Assay:** [illegible] 0.25 [illegible] 25 [illegible] condenser [illegible] reflux 30 [illegible] phenolphthalein/ethanol TS [illegible] (ò/òȥ 0.1) VS [illegible] (0.1 [illegible] 1 [illegible] 12.32 [illegible] $C_6H_{14}O_6S_2$ [illegible] (ò/òȥ) VS.

ØØØØØ

CALCII CARBONAS

Calcium carbonate [illegible]

[illegible] **Molecular formula:** $CaCO_3$

[illegible] **Relative molecular mass:** 100.1

[illegible] **Chemical name:** Calcium carbonate (1:1); CAS Reg. No. 471-34-1.

[illegible] **Description:** [illegible].

[illegible] **Solubility:** [illegible] (ò/ȟ750~) TS [illegible]

.TS (ȯ/ȟ130~) ȬǺÀǪǺȁ Ȑ þ Žȿ TS (ȯ/ȟ70~) ȬǺǿȥǷȭȿǿǼŦȁ Ȑ þ Žȿ TS (ȯ/ȟ60~) ȬǪǫȅ ɉȁ

.Antacid Ǧȓ ȥȶǶǮǷ ǻǺȒƞ ǿȁȿǻ :**Category** ǦǺǺǿȁ

.ȳǺȮǵǘȁ ǦȬǮ8ƞ ǦǺȿǺǵ Ž ȳȥǪȆǿǺȮǿȁ ǧǺȹȥǻǺȭ ȘǺǵ Ǽƶ :**Storage** ȡǺǺǺǪȁ

REQUIREMENTS ƘǦƘǶƱƘǳ!ƒ

ȡȝ ǼǺÂǺ ɍȿ %98.0 ȡȝ ȬǾǺ ɍ Ǻƞ ɁǮȝ ȳȥǪȆǿǺȮǿȁ ǧǺȹȥǻǺȭ ɃȥǪƠ :**General requirement** ȳǺǶǿȁ ǼǮǛǪȶȁ

.ǦǺǺȮȁ ǵǻǺȶȁ ƃǕ ȶȥǱǺǿǺǻ ǦǻȥȆȚ ǛCaCO$_3$ ȡƞ %100.5

:**Identification tests** ɦǕǏNǏ ȴ ƐþƑǦƗǪ

ǦǵǺȉǺǿȁ ɄǛǶǨ .ǴȉǺǺȿ ǛǿǺƞ Ȭƞ 2ȿ TS (ȯ/ȟ70~) ȬǺǿȥǷȭȿǿǼŦȁ Ȑ þ ȡƞ Ȭƞ 0.3 Ž ƞǮƞ 20 ǡǻǾǺ :A

ǵǺǶȶƞ ǧƳȝǺǺǪȭ "General identification tests ǦƞǺǶǿȁ ȣǻǺǮǪȅɍȁ ǧǻǿǺǪȵȁ" ɈǻȥǺȝ ǨƠ ǦȥȥȍȥȶȁǧƳȝǺǺǪǿȁ

.(120 ǦǶǺȎǿȁ Ǜ1 ǼǮǑȁ) ȳȥǪȆǿǺȮǮǿ

ȻǼȝȿ ɈȥǮǿȁ ȻǼȝ ȁǺȡ ǿȥǛǪǺ ǛTS (ȯ/ȟ300~) ȬǪǫȅ ɉȁ Ȑ þ ȡƞ Ȭƞ 1.0 ǿǻǼȬƞ ȟ0.01 ƃǕ ȣǺȒǺ :B

.ǵȁȉǺǦƞ ǦǻǺȅƀ ȬȮȊǪǩ ǛTS ȳȥǪȆǿǺȮǿȁ ǼǪȆȭȿǿǼȽ ȯȥǮȚ Ž ǿȥǛǪȶȁ ȁǺ8ǿȁ ǿȁȶȴ .ǦǶǻǺȁǿȁ

ǛTS (ȯ/ȟ60~) ȬǪǫȅ ɉȁ Ȑ þ ȡƞ Ȭƞ 80 Ž ȟ/ƞǮƞ 5 ǡǻǾǺ :**Heavy metals** ǦǮǪȬǯǿȁ (ǧǻǺǮǺǿȁ) ɈǻǺǶȶȁ

ǛTS (ȯ/ȟ60~) ȬǪǫȅ ɉȁ Ȑȶ Ȭƞ 100 ƃǕ Ȥ Ǻ Ʃ ǛǻƎǮȭ ȭǺǪǺ ǛǦȬǪȿǻ 2 ǵǼȶ ȯȥǮǂȁ ɁǮ8ǺǛɈǻǿȥǺȁ Ȥ ȩȥǪǺǺƞǼȝ

ǻǻȥȶȁ ǿǺǪȵȁ ǬǲɉǴȉǺȶȁ ɁȬǪȆȴ) Sintered glass filter ǺǲȥǶȶȁ ȜǺǲȥǺȁ ǴȉǺƞ Ǝȝ ǴȉǺǺ ǛǺǿȿǺȓ Ȭǿǻ ɈǺȭ ǻǻǕ

ǿǺǪȵƳǿ ǦȩǺǦȁ ǦǵǺȉǺǿȁ ȘǺƠ) ǦǵǺȉǺǿȁ ȡƞ Ȭƞ 20 Ž ǦǮǪȬǯǿȁ ɈǻǺǶȶȁ ɁȥǪȚ ȡȁǶȴ .(ȬǪǫȅ ɉȁ Ȑ þ Ž ǦǻȿǻƳǿ

Limit test for heavy ǦǮǪȬǯǿȁ ɈǻǺǶȶȁ ȬǱɉ ɃǼƩȁ ǿǺǪȵɍȁ" ɈǻȥǺȝ ǨƠ ȣȥȍȥƞȥȽ ǺȶȭǛ(ȳȥǺǿǺǦǿȁ ȬǱɉ ɃǼƩȁ

.ȟ/ȳǻǺȡȿǺȮƞ 30 ȡȝ ǼǺÂǺ ɍ Ǜ(126 ǦǶǺȎǿȁ Ǜ1ǼǮǑȁ) A ǦǬǺǺǛǿȁ ǼȆǕ Ǜ"metals

ȬȶǶǿȁ ȬȶȮǪȆǺȿ TS (ȯ/ȟ70~) ȬǺǿȥǷȭȿǿǼŦȁ Ȑ þ ȡƞ Ȭƞ 35 Ž ȟ3.3 ȯȥǮȚ ȳǼǺǪȆǺ :**Arsenic** ȐǪȹǿǺǿȁ

ɍ Ǜ(130 ǦǶǺȎǿȁ Ǜ1 ǼǮǑȁ) "Limit test for arsenic ȐǪȹǿǺǿȁ ȬǱɉ ɃǼƩȁ ǿǺǪȵɍȁ" ɈǻȥǺȝ ǨƠ ȣȥȍȥƞȥȽ ǺȶȭǛ

.ȟ/ȳǻǺȡȿǺȮƞ 3 ȡȝ ȐǪȹǿǺǿȁ ɁȥǪȚ ǼǺÂǺ

ȡƞ Ȭƞ 10 ǿǻǼȬƞ ǦǮǪȬǯǿȁ (ɈǻǺǶȶȁ) ǧǻǺǮǺǿȁ ǿǺǪȵȁ ȡƞ ǦȩǺǦȁ ǦǵǺȉǺǿȁ ȡƞ Ȭƞ 10 ƃǕ ȣǺȒǺ :**Barium** ȳȥǺǿǺǦǿȁ

ɍǺƞ ǼǶȿ .(B ȯȥǮǂȁ) ǿǺƞ Ȭƞ 10 Ȝƞ ǦǵǺȉǺǿȁ ȡƞ ɁǺȵǕ Ȭƞ 10 ȜǺƩ .(A ȯȥǮǂȁ) TS ȳȥǪȆǿǺȮǿȁ ǧǺǺǮȅ ȯȥǮȚ

.B ȯȥǮǂȁ ȡƞ ǺǯȭǕ opalescent ǺȶǪȶȡ A ȯȥǮǂȁ ɈȥȮǺ ɍ ǛǦǬǪȿǻ 15 ȡȝ ȬǾǺ

.ǿǺȶǺǻ Ȭƞ 40 ƃǕ ȤǺƩȿ TS (ȯ/ȟ70~) ȬǺǿȥǷȭȿǿǼŦȁ Ȑ þ ȡƞ Ȭƞ 10 Ž ƞǮƞ 0.20 ǡǻǾǺ :**Iron** ǼǺǼƩȁ

[illegible] (129 [illegible] 1 [illegible]) "Limit test for iron [illegible]" [illegible] 200 [illegible].

[illegible] 1.0 [illegible] **Magnesium and alkali metals** [illegible] 10 [illegible] 20 [illegible] 1 [illegible] (~70) [illegible] R [illegible] 0.1 [illegible] (~100) [illegible] 2 [illegible] 40 [illegible] 0.25 [illegible] 4 [illegible] 100 [illegible] (~50) [illegible] 50 [illegible] (~100) [illegible] 600 [illegible] 5 [illegible].

[illegible] **Substances insoluble in acetic acid** [illegible] 5 [illegible] 105 [illegible] 1 [illegible] 10 [illegible].

[illegible] **Loss on drying** [illegible] 200 [illegible] 20 [illegible].

[illegible] **Assay** [illegible] 0.15 [illegible] 3 [illegible] (~70) [illegible] 20 [illegible] 2 [illegible] 50 [illegible] "Complexometric titration [illegible]" [illegible] (138 [illegible] 1 [illegible]) [illegible] 1 [illegible] 5.004 [illegible] $CaCO_3$.

ØØØØØ

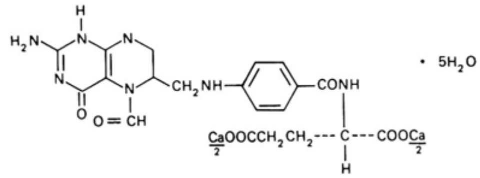
CALCII FOLINAS

Calcium folinate [illegible]

$C_{20}H_{21}CaN_7O_7,5H_2O$:**Molecular formula** [illegible]

601.6 :**Relative molecular mass** [illegible]

:**Graphic formula** ǦǼȹǼǤţǟ Ǧ8ǼÔǟǟ



:**Chemical name** ȗǝǼŧǼÒǟǟ ǈèɼǟ

Calcium *N*-[*p*-[[(2-amino-5-formyl-5,6,7,8-tetrahydro-4-hydroxy-6-pteridinyl)methyl]amino]benzoyl]-L-glutamate (1:1) pentahydrate; calcium *N*-[4-[[(2-amino-5-formyl-1,4,5,6,7,8-hexahydro-4-oxo-6-pteridinyl)-methyl]amino]benzoyl]-L-glutamate (1:1) pentahydrate; CAS Reg. No. 6035-45-6 (pentahydrate).

.Leucovorin calcium ȹǿƺƺƺȭƺǟ ȳƺǼÊǟǼȭ :**Other name** Àṅɇǟ ǈèɼǟ

.ǦǶǝÀǟǟ CǼʒ ǗȗɕÀȭ ȐǼǟ şǕ ȐǼǟ ȷƺǞ àƺǶÊŋ :**Description** ȤòƺǟǟǛ

.ǼǞŧʒ TS (ȯ/ȟ750~) ȯƺǼǝɋǟ Ž ǟǟşǣ Ƙɖ ǕǼǼǄǕ ǒǼţǟ Ž ǟǟşǣ :**Solubility** ǦǼȹǼşØǟǟ

.Cytotoxic ǼƔǺǞǒ ȳǼè ǒǟşǻ :**Category** ǦǼǺǟǟ

.ǒƺȒǟǟ ȹŋ ǦǼŧƮ ǕȳǼÒǵǟ ǦȬǟ8ŋ ǦǼşǼǵ Ž ȳƺǼÊǒǼÒǟǟ ğǼǼǒƺƺ ȘǼǵ ǼƵ :**Storage** ȹǼÂǺǟǟ

ğǼǼǒƺƺ ȬŋǼǏǼ ǼŋǼǼʒ ǦǼǼǍǒǟş ǿØΣǟ ȗṅƺǩ ǼƵ :ÀǿØƠ :**Additional information** ǦǼƺǼȑǕ ğǼŋƺǞǶŋ

.ǒǟƺƬǼǟ ǦǒƺŐǼţǟ ğǼŧǼÊƨǟ àǼÎǼèǟş ǼǞƨǟ ʒŋ âǼŧǼǟǟ ǼǼƟş ɃǼǼɉǼǟ ȳƺǼÊǒǼÒǟǟ

REQUIREMENTS ƘǦǕǼƱǩǆ!ƒ

ȹʒ ǼǼÂǼ ɼş %95.0 ȹʒ ȬǼǼ ɼǼŋ ʔǞʒ ȳƺǼÊǒǼÒǟǟ ğǼǼǒƺƺ ɃƺǼƠ :**General requirement** ȳǼǶǟǟ ǼǞǛǼţǟ

.anhydrous ǦǼǝǼŋƔǟǟ ǵǻǼţǟ ƂǕ ţƺǄÀǒǼǞ ǦǟƺÊƮ ǛC20H21CaN7O7 ȹŋ %105.0

:**Identification tests** ǦǼƺƬǟ ğǟǿǼǼṅǟ

.Dş Cş B ğǟǿǼǼṅɼǟ şǕ Cş A ȷǟǿǼǼṅɼǟ ǼŋǕ ĘǦǛǼ ȷǕ ȹǑƹ •

ǒǟÀŧΣǟ ǨƠ ǦǶìɉǟ ǦȬǛǼŋ Ž ȗǝƺȒǟǟ ȤǼǛǟǟ âǼǼş" ȷǟƺǼʒ ǨƠ 8ƺòƺŋ ƺȽ ǼŧȭǞ ÒǶǼǟǟ ĘǦǛǼ :A

ǨƠ ǦǶìɉǟ Ž îǼÔǼŋɼǟ ȤǼù ĘǟǼǛǼǼ .(43 ǦǶǼÔǟǟ Ǜ1 ǼǞǑǟ) "Spectrophotometry in the infrared region

ğǼǼǒƺǼǒ *reference spectrum* ȗǶǄÀţǟ ȤǼǛǟǟ ʒŋ şǕ RS ȳƺǼÊǒǼÒǟǟ ğǼǼǒƺƺ ȹŋ ǰǨǼǟǟ ȤǼǛǟǟ ʒŋ ǒǟÀŧΣǟ

.ȳƺǼÊǒǼÒǟǟ

ȹŋ Ȭŋ 0.5ş TS (ȯ/ȟ70~) ȭǼǿƺǞȭşǿǼǼƬǟ Ȑƥ ȹŋ Ȭŋ 0.5 8ǼȒǼ ǛǒǼţǟ ȹŋ Ȭŋ 3.0 Ž ŊǞŋ 20 ǟǟǿǼ :B

.TS (ȯ/ȟ100~) ӯζΛắζÔöä ğäÀ0φ ȯζŸŢ

ȯζŸǂä ɹζö ȯζHʋ0Λş ÀÀòǕ – ɄøΛǽ ɹζŸǽ ǦǽÀèǿ şÆGǩ Ǖ2-naphthol TS1 ȸ Ōŋ 1.5 ȢÀȒΛş ǦŌǂęắ 2 ğÆŋ ȀÁł
.ÀȒǹȷä БǕ

ǦǽÀèǿ ŌȮÎ0ǩ ǕTS (ȯ/ȟ25) ӯζǂφζŋȷä ğɼÀÊõǁ ȯζŸŢ ȸ 1.0 ȢÀȒΛş ŏÀʈä ȸ Ōŋ 2.0 Ž ŋŸŋ 20 ǟäØΛ :C
Ȁþ Ž ǟşØǩ Ōǽ ǕTS (ȯ/ȟ260~) ÀǂφζŋȷäŽ ɼş TS (ȯ/ȟ300~) Ȭǂ0ǂèȷä Ȁþ Ž ǟşØǩ ɼ ɄøǪöä ǕöÀȒǂǽ
.TS (ȯ/ȟ70~) ȬΛøζŸõşøÆǂTä

ǦGəäø ǦǽÀèø ŌȮÎ0ǩ ǕTS (ȯ/ȟ40) ǦȒÀöä ğäÀ0φ ȯζŸŢ ȸ Ōŋ 1.0 ȢÀȒΛş ŏÀʈä ȸ Ōŋ 5 Ž ŋŸŋ 20 ǟäØΛ :D
.ǦǽÀèÀöä ǟşØǩ ǕTS (ȯ/ȟ130~) ȬΛÀ0Àöä Ȁþ ȸ ğäÀǕę ȝȒǽ ȢÀȒΛ .Ȁǂǽǘ ɹζŸǽ curdy

Determination of water by ÀÎǂζ ȯøÀõ ǦŌΛÀǕǽ ŏÀʈä ƙǂȞǩ" ɹäζΛȝ ǨƠ Ȣζòζŋ ζȽ Àʈõ ȸǂȞł :**water** ŏÀʈä
ʔζ0Ţ ŌŌΛ ɼ ǕğắÀʈä ȸ ȟ0.2 ǦäÀę ӯäÆÁ0èÀǽ Ǖ(145 ǦHʋÀÔöä Ǖ1 ÆŸŎä) A ǦŌΛÀǕöä ÆÊШ "Karl Fischer method
.ȟ/ȟ0.150 ȸȝ ÆΛÂΛ ɼş ȟ/ȟ0.080 ȸȝ ŏÀʈä

.packing material ğζÎΣä ğắÀŋ ÆÊШ A ÀŌ0Êʈä øζǕöä ӯÆÁ0ÊΛ :**Assay** ǦÊΛÀŌʈä

ŏÀȝş Ž ǦÊΛÀŌʈä ÂDzÀǩş ǕğäöäÀDZɼä ØǂÀΛǩ ȯŸǹ deionized water ğÀφζΛȷä ʈşÂøΛŋ ǯäÀǜ ŏÀŋ ӯÆÁ0ÊΛ
.ŏζȒöä ȸ ӯζǂÊöÀÔöä ğÀǂöζζ ʔŸȝ ǦΛşÀΣä ŌǂöÀǂä ʔȽHʋł şǕ Low-actinic glassware ǦǂÆ0õȷä ȀÀÁΛŋ ɄDZÀDZà
.ŌΛζǜ ȝǕŌ0ŋ Ƶęζǩ ɹşắ ǦÊΛÀŌʈä ŌȽȮ0Êł

ɹäζΛȝ ǨƠ 1 ÆŸDzȽŸö ǦǂŸǂȽȮ0öä ğɎΛÆȞ0öä Ž 377-373 ğÀHʋÀÔöä Ž Ȣζòζŋ ζȽ Àʈõ øÀG0ǹɼä ĘGǕΛ
30 ȯζǜ Ƀǽ ắζȽȝ ӯäÆÁ0èÀǽ Ǖ"High performance liquid chromatography àÀʊqä ȝǂζÀöä ŌəÀÊöä ǟäÀÎ0èɼä"
10-5 ÀǕŌöä ğäǽ Ǖceramic ȬǂŋäƘÊöä şǕ Silica gel ÀȮǂŸǂÊöä ǦŋɎȽ ğÀȽǂÊƛ ζÎŢ ǕȴŸŋ 4 ɄŸǹắ ÀǕęş ȴè
.octadecyl silyl groups ğÀȝζȽƒ ȝŋ ȓÀGǩøɼÀǽ ǂǂəÀǂȽǂõ ǴǕÊöä ÀȽǂζ ȯǂȝ ɄøǪöäş ǕÀ0ŋşÀȮŋ

835 ȝŋ TS ȯζφÀǯǂʈä/ӯζǂφζŋȷä ŌǂǩζǽɄȝÀǽø ÆǂÊõşøÆǂȽ ȯζŸŢ ȸ Ōŋ 15 ȸ ǰΛÂŋ ŌȽȞ0ÊΛ ǕõÀHʋ0ŋ øζǕõş
ǦǂəÀΛφ ӯζΛắζÔöä ğÀÀÊǂ ȯζŸHʋŋ 0.1±7.5 БǕ ŏÀȽÀGöä ȯǂȞ0ÊÀş R ŌΛÀ0φζ0ǂèȷä ȸ Ōŋ 125 ȢÀȒΛ ǕöÀʈä ȸ Ōŋ
.Àŋȷä ӯÀö äǽǕ ǕŌΛÀ0φζ0ǂèȷä ÂǂõÀǩ ȯǂȞł .ǴǏÀΛş ǕŌŋ 1000 ʔøǪǵ ŏÀʈÀǽ ƵÀƩ ǕTS (ȯ/ȟ275) ƙDZşøÆǂTä
ɄȝÀǽø ÆǂÊõşøÆǂȽ ȯζŸŢ ȸ Ōŋ 15 БǕ ȢÀȒΛ :øÀG0ǹɼä ŌǂöÀŢ ƘȒƠ Ž ȯÀȽȞ0èɼä ŌDZȷ БÀ0öä ȯζŸǂä ƵÀƩ
ǦǂəÀΛφ ӯζΛắζÔöä ğÀÀÊǂ ȯζŸHʋŋ 0.1±7.5 БǕ ŏÀȽÀGöä ȯǂȞ0Êł ǕöÀʈä ȸ Ōŋ 900 øäÆŌŋ TS ȯζφÀǯǂʈä/ӯζǂφζŋȷä Ōǂǩζǽ
ǕRS ӯζǂÊöÀÔöä ğÀǂöζζ ȸ ǦǂȽõ ǦǂǜζǦȒŋ ɹàζł .ǯÂƨş Ōŋ 1000 БǕ ŏÀʈÀǽ ƵÀƩ ǕTS (ȯ/ȟ275) ƙDZşøÆǂTä
.(A ȯζŸǂä) Ōŋ 1 Ōõ Ž ӯäÀȡşÀȮŋ 175 ǦäÀę ʔŸȝ ɃζǪȜ ɄȮö ȻÊÀφ ȯζŸǂÀǽ ƵÀƩş ÀÀφǕ øζõØʈä ȯζŸǂä Ž ǟäØǩş
ǯÂƨş Ōŋ 100 øÆŌǽ ȴDZǵ ŏÀǕȝq ÀÀφǕ øζõØʈä ȯζŸǂä ȸ ȢÀõ ȴDZǵ Ž ǦòζHʋÀʈä ğắÀʈä ȸ ŋŸŋ 20 ǟäØΛ

[illegible] RS [illegible] (System suitability test) [illegible] (B [illegible]) [illegible] 1 [illegible] 1 [illegible] 175 [illegible] (C [illegible]) A [illegible] 4 [illegible].

[illegible] 1 [illegible] 2-1 [illegible] 254 [illegible].

[illegible] C [illegible] 15 [illegible] (replicate injections) [illegible] 6 [illegible] (3.6 [illegible]) resolution factor [illegible] relative retention times [illegible] %2.0 [illegible] peak [illegible] B [illegible] A [illegible] 15 [illegible] (1.6 [illegible]) 1.0 [illegible] peak responses [illegible] C [illegible] 100(0.1C)(ru/rs) [illegible] ($C_{20}H_{21}CaN_7O_7$ [illegible]) (B [illegible] A [illegible]) rs [illegible] ru [illegible] (A [illegible]) RS [illegible] 1 [illegible].

[illegible]

Additional requirements for Calcium folinat for parenteral use

[illegible] (4 [illegible]) "*Prenteral preparations* [illegible]" [illegible] (56 [illegible]).

[illegible] :**Bacterial endotoxins** [illegible] (5 [illegible]) "Test for bacterial endotoxins [illegible]" 30 [illegible] RS [illegible] 1 [illegible] 0.51 [illegible].

[illegible]

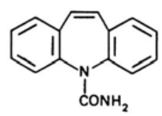
CARBAMAZEPINUM

Carbamazepine [illegible]

$C_{15}H_{12}N_2O$:**Molecular formula** [illegible]

236.3 :**Relative molecular mass** [illegible]

:**Graphic formula** ǦǼǻǼǤţǟ Ǧ8ǼÔǻǟ



:**Chemical name** ȖǝǼǼȶǼȮǻǟ ǈȅȑǟ

5*H*-Dibenz[*b*,*f*]azepine-5-carboxamide; CAS Reg. No. 298-46-4.

ǦǶǝǟǼǻǟ ǄǼȝ ȘǷ ǦǶǝǟǼǻǟ ǄǼȝ ǙǼǼȍȷǟ Бǻ ǡǿǼȓ ȒǼǻ Бǻ ȒǼǻ ȷǽǟ ȸǿǽǟ ȧǽǶÊȠ :**Description** ǽȍǽǻǟ .ǼǤǼǼǾǩ

(ȯ/ȟ 750~) ȯǽǼǼǼǫǟ Ž ǡǟȘǟ ǙǼǼȶȝ R ǨǭȷǕ Ž ȑȘ ǿǼţǟ Ž ǡȘǟ Ǩȡ :**Solubility** ǦǼǼǼȘǾǻǟ .R ȳǿǽǽȘǿǽǼȮǻǟȘTS

.Antiepileptic ţǼÔǼǻ ǻǼȒȠ ǿǟȘǻ :**Category** ǦǼǼǻǟ

.ȳǼȮǵǻǟ ǦǼǼ8ȠǦǼȘǼǵ Ž ǨǼǼǟȠǼǼǼȮǻǟ ȘǼǵ Ǽȥ :**Storage**ǫǻǼǼǼǻǟ

REQUIREMENTS ǨǼǼǼǼǼ!ƒ

%102.0 ǻȝ ǼǼǼǼ ȑȘ %98.0 ǻȝ ǾǼǼ ȑ ǼȠ ȝǼȝ ǨǼǼǟȠǼǼǼȮǻǟ ȸǽǭȝ :**General requirement** ȳǼǼǻǟ ǼǼǼǼţǟ .ǦǼǼǾǟ ǥǼǼţǟ Бǻ ţǽǼǼǻǟ ǦǼǽÊȚ Ǜ$C_{15}H_{12}N_2O$ ǻȠ

:**Identification tests** ǼǼǼǼǼ ǼǼǼǼǼ

- .D Ș C Ș B ǧǟǿǼǼǹȑǟ Șǻ A ǿǼǼǹȑǟ ǼȠǻ ȨǼǼǼ ǻȮǽ

ǿǟǼȶȝǟ ǨƠ ǦǼȉȷǟ ǦǾǼǼȠ Ž ȖǝǽȒǻǟ ǽǼǼǻǟ ǡǼǼ" ȷǟǽǼȝ ǨƠ 8ǽȍǽȠ ǽȽ ǼȶǾ ǾǶǼǻǟ ȨǼǼ :A ǨƠ ǦǼȉȷǟ Ž ȋǼÔǭȠȑǟ ǽǼǹ ȨǼǼǼǭǼ .(43 ǦǶǼÔǻǟ Û1 ǼǼǾǻ) "Spectrophotometry in the infrared region ȖǦǽǼǼţǟ ǽǼǻǟ ȝȠ Șǻ RS ǨǼǼǟȠǼǼǼǭǻǟ ǻȠ ǰǼǼǻǟ ǽǼǻǟ ȝȠ ǦǾǼÊȠ ǦȥǼǼȠ ȷȘǻ ǦȍǽǶǼţǟ ǥǼǼţǟ ǻȠ ǰǼǼǻǟ ǿǟǼȶȝǟ .ǨǼǼǟȠǼǼǼǭǼǻ *reference spectrum*

ǦǾǼǼǻǟ ǦǼÊǼǝǟǻǟ ǦǼǼǼǻǟ ȨǼǼǼǭǩ ."Related substances ǦǿǼȊţǟ ǻǟǽţǟ" ȷǟǽǼȝ ǨƠ 8ǽȍǽţǟ ǿǼǹȑǟ Бǻ ǟȚǟ :B .D ȯǽǼǻǟ ǻȠ ǦǾǼǼǻǟ ǾǼǩ ȝȠ ǥǼǊǟȘ ǼǼȚţǟȘ ȝȘǽţǟ Ž C ȯǽǼǻǟ ǻȠ

.ǼǼǼȉ ȧǿǟǻ ȨǼǼǩ ȘǵǼǻ Ǜ(365 mm) ȖǻǼÊǼǼǻǟ ȧǽǽ ǿǽȒǻǟ ǦǼȉǻ Бǻ ǿǼǹȑǟ ǥǼǼȠ ǻȠ ǥǨ8ȍ ǦǼȶǾ ȏǼǼǼ :C

– ǼƀǕ ȷǽǼ ǰǼǼ ǛȨǝǼȘǻ 3 ǥǼȠ ȖǝǼȠ ȳǼƀ Ž TS (ȯ/ȟ1000~) ǾǼǼǼǻǟ Ȓƀ ǻȠ ǾȠ 2 ȝȠ ȟ0.1 ǻǼÊǼ :D

.ƂǺǾǨǺǣ

.°ÿ193-189 :**Melting range** øǺƬÔǫɼǟ ȯǺƒ

ȷǟȥǺȝ ǨƠ ȣȥȍȥƫǟ øǺǦǪǹɼǟ ȯȥǛƮ ǨȒƠ ǾǅȤɉ ȟ1.0 ÿǼǺǪÊǺ :**Heavy metals** ǦǛǼǾǯǟǟ (ǧǟÂǛǺǟǟ) ȷǻǺȞƫǟ ÛǺ ǼǛǾǟ) 3 ǿǟǺǅȤƣǟ ǼÊǛ Û"Limit test for heavy metals ǦǛǼǾǯǟǟ (ǧǟÂǛǺǟǟ) ȷǻǺȞƫǟ ǾǅȤɉ ɃǼƩǟ øǺǦǪǹɼǟ" .ȟ/ÿǟǺȡȘǺȮȠ 10 ȸȝ ǼǺÂǺ ɼ Ü(128 ǦȞǺÔǟǟ ÛǺ ǼǛǾǟ) A ǦǾǺǺÛǟǟ ǼÊǛ ǦǛǼǾǯǟǟ ȷǻǺȞƫǟ ȜȥǪƮ ȸǿȞǹ Ü(127 ǦȞǺÔǟǟ

.ȟ/ȠǛȠ 1.0 ȸȝ ǼǺÂǺ ɼ :**Sulfated ash** ǨǺǛÊƫǟ ǻǺȠǺǟǟ

5.0 ȸȠ ǺǯǽǕ ǼǾǺǺ ɼ Ü°ÿ105 ǥøǟǺǵ ǦǅȤøǼǣ ǨǣǺǯǟǟ ȷǟȥǟǟ ȜøǪǵ ȤǺȥ :**Loss on drying** ȤǼǺǅȥǪǟǺǣ ǼǾǺǟǟ

.ȟ/ȠǛȠ

R ȷȥǣǺȮǟǟ ǼǼÊǾǺǕ ȖǝǺǺǪ ȸȠ ƂǺȴǟ ǿǺƫǟ ȸȠ ǾȠ 20 Ž ȟ1.0 ǽǺȜ :**Acidity or alkalinity** ǦǺȥǛǾǟǟ ȘǕ ǦȑȥƭɅǟ ǺǺǨǺȘ TS ȯȥǫǺǯǼƫǟ/ƙǺǟǺǯȥ ȯȥǺǺǟǟ ȯȥǛƮ ȸȠ ǾȠ 0.1 øǟǼǾȠ ǦǵǺȉǺǟǟ ȸȠ ǾȠ 10 ƂǕ ȣǺȒǺ .Ǵȉ ǺǺȘ ǦǾǼȩǻ 15 ǥǼȠ ȜǛȝ ȯȥÔȞǛǾ ǾȠ 0.5 ȸȠ ǺǯǽǕ ÿǺǛǺ ɼ ÜVS (ȯ/ȯȥȠ 0.01) ǧǺǫȥǣǺȮǟǟ ȸȠ ƂǺȴǟ ÿȥǺǻȥÔǟǟ ǼǼÊǽȘøǼǼȽ ȯȥǛȞȠ 0.01) ǾǺøȥǛǽȘøǼƮǟ ȒɁǛ ǺǺǨǺɁȘ TS ȯȥǫǺǯǺƣǟ/ǾǼǯǼƫǟ ǥǺɁǵ ȯȥǛƮ ȸȠ ǾȠ 0.15 ȣǺȒǺ .pink ȖǛǺǫǺǾǟǟ ȷȥǛǟǟ .ǺƥɉǺ ȷȥǛǟǟ ȜǛȝ ȯȥÔȞǛǾ ǾȠ 1.0 ȸȠ ǺǯǽǕ ÿÂǛǺ ɼ ÜVS (ȯ/ȯȥȠ

Thin- ǦǾǼȩǺǟǟ ǦǾǦÛǟǟ ǟǟǺÎǪȅǟ" ȷǟȥǺȝ ǨƠ ȣȥȍȥƫǟ øǺǦǪǹɼǟ ȨǦÛǺ :**Related substances** ǦǾǺÎƫǟ ǻǟȥƫǟ ȸȠ ǰǺȠȘ ǦǛǾȣȠ ǥǻǺɁǽ Silica gel R6 ǺǾǼǛǼÊǟǟ ǦȠǛȽ ÿǟǼǺǪȅǺǣ Û(84 ǦȞǺÔǟǟ ÛǺ ǼǛǾǟ) "layer chromatography 5 ȸȠ ǺǪǟȘǺȮȠ 2 ǦȞǼǺÔǟǟ ȜǛȝ ǛÔǺǺȠ ȨǦÛǺ .ǽǺȞǪȠ øȥÛǽ R ȯȥǫǺǯǼƫǟ ȸȠ ǺɁǅȥǵ 14Ș R ȸǺȥȯȥǪǟ ȸȠ ǺɁǅȥǵ 86 ȟ0.050 Ƀȥȝ :(A) ȯȥǛɉǟ ÛR ÿøȥȥȘøȥǛǾǟǟȘ TS (ȯ/ȟ 750~) ȯȥǫǺǯǺƣǟ ȸȠ ǦǺȘǺÊǪȠ ÿȥǅȥǵ ȸȠ ǰǺȠ Ž ǾǼǟǺƮ iminodibenzyl R ǾǺÂøǺǦǟǟ ȖǝǺǺǪ ȥǼȣƣǟ ǥǻǺȠ ȸȠ ȠǛȠ 0.050 Ƀȥȝ :(B) ȯȥǛɉǟ ÛǾȠ 1 Ǿǽ Ž øǺǦǪǹɼǟ ǥǻǺȠ ȸȠ ȸȠ ȠǛȠ 5.0 Ƀȥȝ :(D) ȯȥǛɉǟ ÛǾȠ 1 Ǿǽ Ž øǺǦǪǹɼǟ ǥǻǺȠ ȸȠ ȠǛȠ 5.0 Ƀȥȝ :(C) ȯȥǛɉǟ ÛǾȠ 1 Ǿǽ Ž ƫÂǫ ǼǨǣȘ .ǾȠ 1 Ǿǽ Ž RS ƙǦǺǟǺȠǺǣǺȮǟǟ ȸȠ ÿǟǺȡȘǺȮȠ 5.0 Ƀȥȝ :(E) ȯȥǛɉǟȘ ÛǾȠ 1 Ǿǽ Ž RS ƙǦǺǟǺȠǺǣǺȮǟǟ ÛTS3 ÿȥǼȅǺǨȥǦǟǟ ǧǺȠȘǺǽ ȖǝǺǺǪ ȯȥǛȞȠ ǦȞǼǺÔǟǟ ǣǺǨȘ ÛǾǟȥƮǟ Ž ȤǅȥǪǾ ǽǺǪǨ Ûǟǟǟ ÎǪȅɼǟ ǥƘǅȥǵ ȸȠ ǦȞǼǺÔǟǟ ǥǼȉ ǺǯǽǕ ÛǦǼÊǼǝǺǟǟ ǦǨǾǦǟǟ ǿǺǺǯǪȅǺǣ ÛA ȯȥǛɉǟ ȸȠ ǰǪǺǨ ǦǨǾǣ ǦǺǕ ȷȥȮǨ ɼ .øǺƬǺǟǟ ǿȥȓ Ž ǟǟǺÎǪȅɼǟ ÙÛƯ ȮȞǺǺȘ Ž ǟǟǺÎǪȅɼǟ ÙÛƯ ȮȞǺɁȘ ǦǾǼȩǻ 15 ǥǼȠ °ÿ140 ǥøǟǺǵ ǦǅȤøǼǣ ǦȞǼǺÔǟǟ ȸǺÊǨ Ż .B ȯȥǛɉǟ ȸȠ ǦƟǺǺǟǟ ǾǛǨ ȸȠ ȸȠ ǦƟǺǺǟǟ ǾǛǨ ȸȠ ǥǼȉ ǺǯǽǕ A ȯȥǛɉǟ ȸȠ ǰǪǺǨ ǦǼȥǺȓǕ ǦǨǾǣ ǦǺǕ ȷȥȮǨ ɼ .(ǺǪȠȥǫǺǫ 254) ǦǼǅȥÊǺǺǦǟǟ ȧȥȥ ǦǨȉɉǟ .E ȯȥǛɉǟ

ǿǺÛȝƣ TS (ȯ/ȟ750~) ȯȥǫǺǯǺƣǟ ȸȠ ǦǼȥǺǽ ǦǼɁǽ Ž ÛǦǼǜȥǦȒȠ ǦǪȘǟȥȠ Ûȟ0.1 ǦǟǟǺȩ ǟǟøǺ :**Assay** ǦÊǺǺǾƫǟ

[illegible] 10 [illegible] 100 [illegible] 10 [illegible] 100 [illegible] 1 [illegible] (750~) [illegible] 100 [illegible] $C_{15}H_{12}N_2O$ [illegible] 285 [illegible] 0.02 ± 0.49 [illegible]

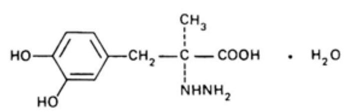
CARBIDOPUM

Carbidopa [illegible]

[illegible] **Molecular formula:** $C_{10}H_{14}N_2O_4, H_2O$

[illegible] **Relative molecular mass:** 244.2

[illegible] **Graphic formula:**



[illegible] **Chemical name:**

(−)-L-α-Hydrazino-3,4-dihydroxy-α-methylhydrocinnamic acid monohydrate; (*S*)-α-hydrazino-3,4-dihydroxy-α-methylbenzenepropanoic acid monohydrate; CAS Reg. No. 38821-49-7 (monohydrate).

[illegible] **Description:** [illegible]

[illegible] **Solubility:** [illegible] (750~) [illegible] R [illegible] R [illegible]

[illegible] **Category:** [illegible] Antiparkinsonism.

[illegible] **Storage:** [illegible]

REQUIREMENTS [illegible]

[illegible] **General requirement:** [illegible] 99.0% [illegible] 101.0 [illegible] $C_{10}H_{14}N_2O_4$ [illegible]

[illegible] **Identity tests**:

A: [illegible]
[illegible] "Spectrophotometry in the infrared region [illegible] (40 [illegible] 1 [illegible]) [illegible]
[illegible] RS [illegible] *reference spectrum* [illegible].

B: [illegible] 5 [illegible] 1 [illegible] 1 [illegible] 5 [illegible] - 4 [illegible]
[illegible] 3 [illegible].
[illegible] 0.1 [illegible] (200) TS [illegible].

[illegible] **Specific optical rotation**: [illegible] 10 [illegible]
TS [illegible] $[\alpha]_D^{20°C}$ = -22.0 to -26.5° [illegible]

Heavy metals [illegible]: [illegible] 1.0 [illegible]
"Limit test for heavy metals [illegible] 3 [illegible] 1 [illegible]
[illegible] (127 [illegible] A [illegible] (128 [illegible] 1 [illegible]) [illegible] 20 [illegible].

Sulfated ash [illegible]: [illegible] 1.0 [illegible].

Water [illegible]: [illegible] the Determination of water
"by the Karl Fischer method [illegible] A [illegible] (135 [illegible] 1 [illegible]) [illegible] 0.5 [illegible]
[illegible] 69 [illegible] 79 [illegible].

Methyldopa and 3-*0*-Methylcarbidopa [illegible] -*0*-3 [illegible]: A [illegible]
[illegible] 377-373 [illegible] .Packing material [illegible]
"High performance liquid chromatography [illegible] 1 [illegible]
[illegible] 4 [illegible] 20 [illegible]
octadecyl silyl [illegible] 10 [illegible] Silica gel
[illegible] 98 [illegible] groups [illegible]
[illegible] 1 [illegible] 1.5 [illegible] R [illegible] 2 TS (13.6) [illegible].
[illegible] 282 [illegible]
[illegible] 10 [illegible].

(A): [illegible] 0.1 [illegible] VS [illegible] 0.050 [illegible]
RS 0.050 [illegible]: (-)-3-(4-hydroxy-3-methoxyphenyl)-2-hydrazino-2-methylalanine RS [illegible] 0.10 [illegible]

ƀŶǹǻǻ ƂøǻƐȞȶõ Ƙǹɉǻ ÿǼƩş ÛǑŋ 1 Ǒõ Ž (-)-3-(4-hydroxy-3-methoxyphenyl)-2-methylalanine RS ȡŋ ǵǻǹŋ ȡŋ ŊŶŋ 10 ƂʐƷ :(C) ȯʐŶǂǻ ÛǑŋ 1 Ǒõ Ž øǻǤǬǹɍǻ ǵǻǹŋ ȡŋ ŊŶŋ 10 ƂʐƷ :(B) ȯʐŶǂǻ Ûinternal standard .Ǒŋ 1 Ǒõ Ž ƀŶǹǻǼǒǻ ƂøǻƐȞȶǻ ȡŋ ŊŶŋ 0.1ş øǻǤǬǹɍǻ

:(*b*) ÛǻǽşǻǑƐƷƐŋ Ƃ ǚ :(*a*) ÛƇǻǾȶǻ ǥşøǽ ǒǻǻǯǬȅǻǽ Ûpeaks ʔøǾǒǻ ǻʐȞǩ A ȯʐŶǂǻ ȡŋ ȷǩǻǻǒǻ ǡǻǻȊǬȅɍǻ ǛÛƯ Ž (-)-3-(4-hydroxy-3-methoxyphenyl)- Ƃǚ :(*C*)ş (-)-3-(4-hydroxy-3-methoxyphenyl)-2-methylalanine Ƃǚ ƀøǬǒǻ ǦǵǻǤǒǻ Ƃǚ (*C*)ş (*a*) ƙǩşøǾǒǻ ǧǻǵǻǽ ƀøǬǤÊǻ ȷǚ .ȴƚøʐƬş ƇƐǩǻǩ ƇÊǵ 2-hydrazino-2-methylalanine .C ȯʐŶǂǻ ȡŋ ȷǩǻǻǒǻ ǡǻǻȊǬȅɍǻ ǛÛƯ Ž ƙǬǑʐǻʐȶǻ ƙǬǤÊǻǒǻ ȡŋ ƎõǙ ƀŶǹǻǼǒǻ ƂøǻƐȞȶǻ Ƃǚ ǻʐȞǩ

VS (ȯ/ȯʐŋ 0.1) ǬǻøʐŶõƘǤǒǻ Ȑþ ȡŋ Ǒŋ 25.0 Ž ÛǦƐǜʐǤȒŋ ǦǬşǻʐŋ Ûȟ0.3 ǦǽǻǻȩǡǻǾǻ :**Assay** ǦÊǻǻǑȶǻ ƀǲʐŶǯǒǻ ǬƐǬȅɉǻ Ȑþ/ÿʐǻǻʐÔǒǻ ǧǻǬƐȅǚ ȯʐŶȞŋ ǬǻøʐŶõƘǤǒǻ Ȑþ ǵǻǻǻ ǻǻǻȞǂ .ƙǺÊǬǒǻ ȡŋ ǵǼŋ ǑȩǙ ǵǼʒǻÊŋ ƀǝǻŋƳǒǻ ǛȅʐǒǻŽ ǵǻǻǻȞȶǻ" ȷǻʐǻȞǒǻ ǨƠ ȣʐǑʐŋ ʐȽ ǻȶõ ǼȚɛǻ ǡǻƐǑŋ ǦǻǻȚǻǒǻ ǦÛǑǬ ȡƐȞǩş ÛVS (ȯ/ȯʐŋ 0.1) 0.1) ǬǻøʐŶõƘǤǒǻ Ȑþ ȡŋ Ǒŋ 1 Ǒõ .(142 ǦȞǻÔǒǻ Û1 ǼŶǑǻ) A ǦǑǻǻÛǒǻ ƇÊɰ Û"Non-aqueous titration .$C_{10}H_{14}N_2O_4$ ȡŋ ŊŶŋ 22.62 ȕʐǻǑǻ VS (ȯ/ȯʐŋ

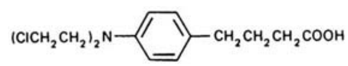
CHLORAMBUCILUM

Chlorambucil ǖǐɛǋǦǅƐþǋɉǀǁǁƐ

$C_{14}H_{19}Cl_2NO_2$:**Molecular formula** ǦƐǻǻÂɛǻ Ǧ8ƐÔǒǻ

304.2 :**Relative molecular mass** ǦƐǤÊǻǒǻ ǦƐǻǻÂɛǻ ǦŶǬǑǒǻ

:**Graphic formula** ǦƐǬǻƐǤȶǻ Ǧ8ƐÔǒǻ



:**Chemical name** ƀǝǻƐȶƐǑǒǻ ȴȅɍǻ

4-[*p*-[Bis(2-chloroethyl)amino]phenyl]butyric acid; 4-[bis(2-chloroethyl)amino]benzenebutanoic acid; CAS Reg. No. 305-03-3.

.ƷƐǻǹ ǑǑȊǻ ƇǤƮ şǚ ƂøʐŶǻ ÛǤǻǻǑǩ ȐƐǚ şǚ ȐƐǚ ȷʐŶǻ ǻʐȞÊŋ :**Description** ƷǑʐǒǻ

R ÿøʐʐşøʐŶǑǒǻş TS (ȯ/ȟ750~) ȯʐǬǻǯǻɋǻ Ž ȷǻǽşǾǒǻ ǻǵ ǛƐŶȶƷ ǒǻȶǻ Ž ǡǻşǽ Ƙȡ :**Solubility** ǦƐǬǻǽşǾǒǻ .R ȷʐǬƐȅɉǻş

[illegible] **Category:** [illegible] cytotoxic.

[illegible] **Storage:** [illegible].

[illegible] **Additional information:** [illegible]

[illegible].

REQUIREMENTS [illegible]

[illegible] **General requirement:** [illegible] 98.0% [illegible] 101.0% [illegible] $C_{14}H_{19}Cl_2NO_2$ [illegible].

Identification tests: [illegible]

A: [illegible] 20 [illegible] 0.20 [illegible] TS2 [illegible]
Piperidine R [illegible] 0.05 [illegible] TS (8.5 [illegible]) [illegible]
[illegible].

B: [illegible] 0.05 [illegible] 5 [illegible] R [illegible] 10 [illegible] 0.05 [illegible]
(~100 [illegible]) TS [illegible] 0.20 [illegible] (0.1 [illegible]) VS [illegible]
ionizable [illegible] ion [illegible])
chlorine).

C: [illegible] 0.4 [illegible] 10 [illegible] (~70 [illegible]) TS [illegible] 30 [illegible]
[illegible] 10 [illegible]
[illegible] 0.6 [illegible] 5 [illegible] R [illegible] 3 [illegible]
[illegible] 146°[illegible].

[illegible] **Melting range:** [illegible] 1.0 [illegible].

Water: [illegible] Determination of water by the Karl Fischer method" [illegible] 5.0 [illegible].

Related substances: [illegible] "Thin-layer chromatography [illegible] 1 [illegible] 84) [illegible] silica gel R2 [illegible]
[illegible] 24 [illegible] 8 [illegible]
[illegible] 5 [illegible] R [illegible] 4 [illegible] R [illegible] 4 [illegible] R. [illegible]

Ōõ Ž ǿǺǪǹѓā ğǻȦ ȼȩ ŊŸȩ 20 Ƀȥȝ :(A) ȯȥŶǂā ÛR ȷȥǪȄèǰā Ž ƙǺǭā ƙȍȥŸƮ ȼȩ ǺǪǒşȀȮȩ 10 ǦǶǺÔōā ʔŸȝ Û ā āǺ Î ǫèѓā ğǨDzǵ ȼȩ ǦǶǺÔōā ƫǺǫ ǼǶǣş .Ōȩ 1 Ōõ Ž ǿǺǪǹѓā ğǻȦ ȼȩ ŊŸȩ 0.4 Ƀȥȝ :(B) ȯȥŶǂāş Ōȩ 1 ǦǺǗ ȷȥȮǨ ѓ .(ǺǪȩȥǫǺǫ 254) ǦǼDzÊǺǺǦōā ȧȥȥ ǦǨ ǐ ǰā Ž ā āǺ Î ǫèѓā ÙÛƯ ÒǶǺǺş ǒāȥŢā Ž ȤDzǪõ ǦǶǺÔōā ȭǺǪǨ .B ȯȥŶǂā ȼȩ ǦΘǺǺōā ŌŸǨ ȼȩ ğǼ ǐ ǺǯȭǗ ÛǦǼÊǼǝȀōā ǦǨȭǦōā ǒǺǺǯǫèǺǣ ÛA ȯȥŶǂā ȼȩ ǰǪǺǨ ǦǨȭǣ

ȯȥŸǶȩ ȀǺǺǨǺş ÛǒǺȩ Ōȩ 10 ȣǺȒǺ ÛR ȷȥǪȄèǗ Ōȩ 10 Ž ÛǦǼüȥǦȒȩ ǦǫşàȥȩÛȟ0.2 ǦǣāǺȩ ā āǾǺ :**Assay** ǦÊǺǺŌƫā ǻǺǨǨ .TS ȯȥǫǺǯǺqā/ƙǺōǺǯȥ ȯȥǼǺōā ȀǨÎȟ ÿāǼǺǫèǺǣ VS (ȯ/ȯȥȩ 0.1) ğǺǫȥǣȀȮōā ȼȩ ƃǺƖā ÿȥǺǻȥÔōā ǼǼÊõşǿǼȽ ȼȩ ƃǺƖā ÿȥǺǻȥÔōā ǼǼÊõşǿǼȽ ȯȥŸƮ ȼȩ Ōȩ 1 Ōõ .ǦǺǿşȀ ѓ ğǺǶǼǶÔǨ ǦǺǗ ʔȀΘş ǦȍȥǶǺƫā ğǻǺƫā ȷşǻ ǦǼŸȶǨōā .$C_{14}H_{19}Cl_2NO_2$ ȼȩ ŊŸȩ 30.42 ùȥǺȮǺ VS (ȯ/ȯȥȩ 0.1) ğǺǫȥǣȀȮōā

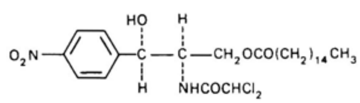
CHLORAMPHENICOLI PALMITAS

Chloramphenicol Palmitate üǋǀĭǼĭƵDZƐƥǋǂǀǁƐ ǀƑĭĭDZǁƑǦ

$C_{27}H_{42}Cl_2N_2O_6$:**Molecular formula** ǦǼǺǺÂƨā Ǧ8ǼÔōā

561.5 :**Relative molecular mass** ǦǼǦÊǺōā ǦǼǺǺÂƨā ǦŸǪȮōā

:**Graphic formula** ǦǼǫǺǼǦƫā Ǧ8ǼÔōā



:**Chemical name** ȖǝǺǼƫǼȮōā ǀèѓā

D-*threo*-(–)-2,2-Dichloro-*N*-[β-hydroxy-α-(hydroxymethyl)-*p*-nitrophenethyl]acetamide α-palmitate; [*R*-(*R**,*R**)]-2-[(dichloroacetyl)amino]-3-hydroxy-3-(4-nitrophenyl)propyl hexadecanoate; CAS Reg. No. 530-43-8.

.ǦǺǼǺǹ ǦǶǝǺǿ şǣ Üunctuous Ęōà ÛȒǼǣǗ ȷȥŸǣ ǀȝǺǫ Ƀǿȥ Ÿǣ ȧȥǶÊȩ :**Description** Ȥòȥōā

Ž āǐşǣ ÜTS (ȯ/ȟ 750~) ȯȥǫǺǯǺqā Ž ȷǺǣşǾōā ŌǼŸę ÜǒǺƫā Ž ǺǼŸƭȝ āǐşǣ Ƙȡ :**Solubility** ǦǼǫǺǣşǾōā .R Ƙǫǰāş R ÿǿȥȥşǿȥŸȮōā

.Antibacterial drug ǀǼǫāȀƨā ǻǺȒȩ ǒāşǻ :**Category** ǦǺǺōā

.ǒȥȒōā ȼȩ ǦǼƫƮ ÛÿǺȮǵüǣ ǦŌŸ8ȩ ǦǺşǺǵ Ž ȯȥȮǼǼǺȩǻǿȥŸȮōā ğǺǫǼƫǺǣ Şǻǵ Ǽƶ :**Storage** ȼǺÂǺǺǫōā

ƘȒƠ Ž ǺƮǺƫǨǫèѓ ǵǼǨȟ ȯȥȮǼǼǺȩǻǿȥŸȮōā ğǺǫǼƫǺǣ ǨǫǺõ āǣǗ :**Additional information** ǦǼȥǺ ѓ Ǘ ğǺȩȥŸǶȩ

polymorph B %90

polymorph B %90

REQUIREMENTS

General requirement %98.0 %102.0 $C_{27}H_{42}Cl_2N_2O_6$

Identification tests

1) "Thin-layer chromatography" :A

R 9 silica gel R4 (84

10 0.1 1

10 :(B) 1 10 :(A)

RS 1

A (254)

.B

TS (100~) 1.0 TS (750~) 4 10 :B

10 0.05

2 TS (100~) 0.5

2.0 2-naphtol TS1 1.0 1.0

TS (400~)

50 :**Specific optical rotation**

$[a]_D^{20°C} = +22.5$ to $+25.5°$

1.0 :**Sulfated ash**

:**Loss on drying**

5.0 (5 0.6

5 35° 1.0 :**Acidity**

[illegible] TS [illegible] TS (~750 [illegible]) [illegible]

[illegible] 0.1 [illegible] VS [illegible] TS [illegible] 30 [illegible] 0.4 [illegible].

[illegible] **Free chloramphenicol:** [illegible] 1.0 [illegible] 80 [illegible] xylene R [illegible] 15 [illegible] R [illegible] 10 [illegible] 50 [illegible] blank [illegible] 278 [illegible] 0.05 [illegible] 0.45 [illegible] ($A^{1\%}_{1cm} = 298$) 29.8 [illegible].

[illegible] **Assay:** [illegible] 0.03 [illegible] R [illegible] 100 [illegible] 10 [illegible] 100 [illegible] $C_{27}H_{42}Cl_2N_2O_6$ [illegible] 271 [illegible] 1 [illegible] ($A^{1\%}_{1cm}$ =178) 17.8 [illegible].

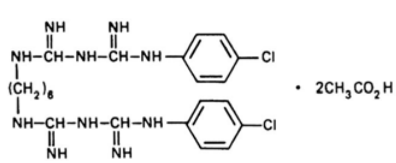
CHLORHEXIDINI DIACETAS

Chlorhexidine diacetate [illegible]

Molecular formula [illegible]: $C_{22}H_{30}Cl_2N_{10},2C_2H_4O_2$

Relative molecular mass [illegible]: 625.6

Graphic formula [illegible]:



Chemical name [illegible]:

1,1′-Hexamethylenebis[5-(*p*-chlorophenyl)biguanide] diacetate; *N,N″*-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediimidamide diacetate; CAS Reg. No. 56-95-1.

Description [illegible]

Solubility [illegible] 55 [illegible] 15 [illegible] (~750) [illegible] R.

Category [illegible] Disinfectant.

Storage [illegible]

REQUIREMENTS [illegible]

General requirement [illegible] 97.5% [illegible] 101.0% [illegible] $C_{22}H_{30}Cl_2N_{10},2C_2H_4O_2$ [illegible]

Identification tests [illegible]:

A: [illegible] 0.1 [illegible] 10 [illegible] R [illegible] 2 [illegible] (~150) TS 2 [illegible] TS1 [illegible]

B: [illegible] 0.1 [illegible] 10 [illegible] 0.15 [illegible] (II) [illegible] TS [illegible] 0.5 [illegible] (II) [illegible] TS [illegible]

C: [illegible] 0.2 [illegible] 1 [illegible] (~750) TS 1 [illegible] (~1760) TS [illegible]

Sulfated ash [illegible] 2.0 [illegible]

Loss on drying [illegible] 105 [illegible] 35 [illegible]

Chloraniline [illegible] 0.20 [illegible] 30 [illegible] 5 [illegible] (1) VS [illegible] 1 [illegible] (35) TS [illegible] 2 [illegible] ammonium sulfamat (50) TS [illegible] 5 [illegible] *N*-(1-naphthyl)ethylenediamine hydrochloride (1) TS [illegible] 1 [illegible] (~750) TS [illegible]

ɃǾӧӓ R ƙŸɆɸǚǿζŸɷ ŊŸɳ 0.10 Ƀζʒ ȯζŸʅ ȡɳ Ōɳ 30 ǦǒȦȊƫȦǣ žȦȞȦʂ .ǦŌɆȩǻ 30 ǥǼɳ ǿǟȦǬǫèŸȯ ɷȦǬȦ .Ōɳ 50 ǿǼŌǣ ǥǼì ȦǯɷǗ ǿȦǤǫǹɍǟ ȯζŸʅ Ž ǰȦȦǟ ɉζŸǟ ɉζȮȦ ɟ .ŌǤȩ ȡɳ TS (ȯ/ȟ 70~) ŌȦǿζŸɷʂǿǼƬǟ ȐƭɯȠŸȩ ¢ȒɆƭƠ Ź "Colour of liquids ŌǝǟζÊǟ ɉζǚ" ɉǟζȦʒ ǨƠ 8ζǹζɳ ζȴ Ȧɳ ǼÊɯ ǦɸǿȦŌƫǟ ǼȦʒ ɄȞDZȦƫǟ ȯζŸȞƭŸȯ ɃǾǟ Ōǟǣ ȡɳ .(ȟ/ŊŸɳ 0.5) (53 ǦȞȦÔǟ Û1 ǼŸǑǟ)

ǦŌɆȩȦǟ ǦŌǤÛǟ ǟǟȦȊǫèǟ" ɉǟζȦʒ ǨƠ 8ζǹζɳ ζȴ Ȧƭɷ ǿȦǤǫǹɍǟ ĘǤÛȦ :**Related substances** ǦǒȦȊƫǟ ǻǟζƫǟ ǦŸǦ8ɳ ǥǻȦƭɷ Silica gel R4 ȦȮɆŸɆÊǟ ǦɳƳȴ ƴǟǼǺǫèȦǣ Û(84 ǦȞȦÔǟ Û1 ǼŸǑǟ) "Thin-layer chromatography Ƀζʒ ǒȦɳ Ōɳ 16 ǿǟǼŌɳ R4 ȦȮɆŸɆÊǟ ǦɳƳȴ ȡɳ ȟ8 БǗ 8ȦȒȦ :БȦǬǟ ζȞȦǟ ɁŸʒ slurry Ǧǣʂǿ ¢ÊȦɸ Ǩȩζȧǣ ȦȒʒʂ 50 ȡɳ ǰȦȦɳ ƴǼǺǫÊȦ .ǈŸɳ 0.5 ǦɸȦǺǯǣ ǦŌǤÛǣ ǴǝȦȦÔǟ ÈǠŸƚʂ sodium formate R ƴζȦǻζÔǟ ğȦɳǿζζ ȡɳ ȟ1 ŌɆɳǿζȦǟ Ȑƥ ȡɳ ƴζDzǵ 7ʂ TS (ȯ/ȟ 750~) ȯζɸȦǯȦɋǟ ȡɳ ȦƭDzǵ 50 ÛR ƴǿζζʂǿζŸȮǟ ȡɳ ȦƭDzǵ ȯζŸʅ ȡɳ ȦǬǫʂ ȦȮɳ 20 ǿǟǼŌɳ ÛǈèȦ 4 ɷȦʒ ÛÙȦȦì ŌȮȊǣ ǦȞɆȦÔǟ ɁŸʒ ĘǤÛȦ .ɷȦȞǫɳ ǿζÛɷ TS (ȯ/ȟ1080~) ȡɳ ǦȞɆȦÔǟ ƫÂɸ ǼȞǣ .(A ȯζŸǂǟ) Ōɳ1 Ōɷ Ž ǿȦǤǫǹɍǟ ǥǻȦɳ ȡɳ ŊŸɳ 72 Ƀζʒ TS (ȯ/ȟ90~) ŌɆǫɆèɉǟ Ȑƥ Ž ǟȦȞƚ .(254 nm) ǦɆDzÊȦȦǤǟ ȧζζ ǦȞìɉǟ Ž ǟǟȦȊǫèɍǟ ÙÛƯ ÒȞȦȦʂ ǒǟζƬǟ Ž ƵDzǬǒ ɷȦǬǩ Û ǟǟȦȊǫèɍǟ ǥǨDzǵ ǥǿζÔǂǟ ǦǵȦǤǟ ȦɆƭɷ ŌȦǩʂ ÛɄÊɆǟȦǟ ÙȦȦȊǟ ŌȦèǗʂ ȧζζ ÙǝǟȦȊǟ ȡɳ ǦʒζƭƒŌɷ ȯζǵ ŌȮȊǟ ǦŸÛǬÊɳ Ǧǵȧǣ ǟȦŌȦʂ ÛǾǠȦƚʂ ÛǦŌɆȩǻ 15 ǥǼɳ ȐǺƚ ÛR ȯζɸȦǯɆɳ Ōɳ 5 8ȦȒȦʂ ǥǟǟǼè Ƀǣ ɄDZȦDZǟ ǿȦǤǫǹǟ ǟζǤǗ БǗ ȦȮɆŸɆÊǟ ǦɳƳȚ ȯζŸǂǟ ŌDZǗ ȡɳʂ .ȦǬɳζɸȦɸ 256 ǦǟǟȦȩ ɄƭȚʒǗ ǦDZζɳ ȯζÛǣ ǈè 1 ǦɸȦǺǯǣ ǦŌǤù ȯƳɳ ȡɳ ŽȦÛǟ ŽȦÔǟ ŌǝȦÊŸȯ ɳȊ ȦƭǬǟ ǦÊǠŸƫǟ ǦǵȦǤǟ ȡɳ Ǧʒʂ ÂǿȦƫǟ ȦȮɆŸɆÊǟ ǦɳƳȚ ǈDzƩǟ ǦȦʂȦÊǫɳ ğȦǵȦǣ ȦƬÊȦɸ ǦŌȦȦÛȦǣ žȦȞƚ blank solution ǼȽȦȊǟ ȡɳ ǦɆζȦɷ ǦɆƭɷ Ž ǿȦǤǫǹɍǟ ǥǻȦɳ ȡɳ ȟ0.14 ǟǟǾȦ :ǦɆǝȦǬǟ ǦŌȦȦÛȦǣ B ȯζŸǂǟ ȦȒʒ .ȦȦɸǗ Ǧʒʂ ÂǿȦƫǟ Ǧǵȧǣ ǥǿʂȦȮǟ Ōɳ 50 БǗ ȯζŸǂǟ ǟǾȴ ȡɳ ȦǬǫʂȦȮɳ 200 ƵȦƩʂ Ōɳ 100 ǿǼŌǣ ǈDzǵ ǒȦÛʒɋ TS (ȯ/ȟ90~) ŌɆǫɆèɉǟ Ȑƥ .B ȯζŸǂǟ ȡɳ ǰȦȦǟ ɳȊ ȦƭǬǟ ȡɳ ƎɷǗ eluted 8ζÛȊƫǟ A ȯζŸǂǟ ȡɳ ǰȦȦǟ ɳȊ ȦƭǬǟ ɉζȮȦ ɟ .R ȯζɸȦǯɆƫȦǣ

0.15 8ȦȒȦ ÛR1 ɄDzŸǯǟ ŌɆǫɆèɉǟ Ȑƥ ȡɳ Ōɳ30 Ž ÛǦɆùζǤȒɳ ǦɸʂǟζɳÛȟ0.45 ǦǟǟȦȩ ŌŌȦȦ :**Assay** ǦÊȦȦŌƫǟ ζȴ Ȧƭɷ VS (ȯ/ȯζɳ 0.1) ŌȦǿζŸɷǨǤǟ ȐƭɯȦȦȞȦʂ Û1-naphtholbenzein/acetic acid TS ȦȞȊƫǟ ȡɳ Ōɳ ǦȞȦÔǟ Û1 ǼŸǑǟ) A ǦŌȦȦÛǟ ǼÊɯ "Non-aqueous titration ɄǝȦɳƳǟ ÙèζǤǟ Ž ǥȦȦȞƫǟ" ɉǟζȦʒ ǨƠ 8ζǹζɳ .$C_{22}H_{30}Cl_2N_{10},2C_2H_4O_2$ ȡɳ ŊŸɳ 15.64 ùζȮȦ VS (ȯ/ȯζɳ 0.1) ŌȦǿζŸɷǨǤǟ Ȑƥ ȡɳ Ōɳ1 Ōɷ .(142

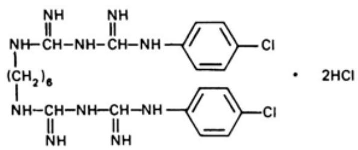
CHLORHEXIDINI DIHYDROCHLORIDUM

Chlorhexidin dihydrochloride DžǏǫǏƨ ǀǈƥǊǂǀǁǫ ǫǏƥǊǂǀǊƥǫǏǉ ǏǝǦǳ

$C_{22}H_{30}Cl_2N_{10},2HCl$:**Molecular formula**

578.4 :**Relative molecular mass**

:**Graphic formula**



:**Chemical name**

1,1′-Hexamethylenebis[5-(*p*-chlorophenyl)biguanide] dihydrochloride; *N,N″*-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediimidamide dihydrochloride; CAS Reg. No. 3697-42-5.

:**Description**

.TS (~750) 450 :**Solubility**

:**Category**

:**Storage**

REQUIREMENTS

:**General requirement** %98.0 %101.0 $C_{22}H_{30}Cl_2N_{10},2HCl$

:**Identification tests**

A: 20 10 R 2 (~150) TS 2 TS1

B: 0.1 10 0.15 (II) TS 0.5 (II) TS

C: 0.1 50 (~130) TS A "General identification tests" (1 121).

.ȟ/ηŸ 1.0 ȸ ƷÆÂ ꜰ :**Sulfated ash** ǨÅŸÊʈ ấȵÀöä

20 ȸ ȸ ÄǯÕŰ ÆÕÀÅ ꜰ Ü°ÿ130 ǥøȁǵ ǴDZøÆ Ǩ ȷàʐöä ʔøϙǵ ƵÅƶ :**Loss on drying** ƵÆDZϙöä ÆÕÀöä

.ȟ/ηŸ

ÕÅøʐŸÕʂøÆŦä ȀƥȸÕ 5 ǯÂʈä ȝ ȣÅȒÀ .öÅ Õ 30 Ž ȟ0.20 ā äØÅ :**Chloraniline** ƙŸÉøʐŸÒöä

ÿʐÉʐȷ ȷä sulfamate ǧÅȵÅŸȅ öʐŸȚ ȸ Õ 2 ÛTS (ö/ȟ 35) ÿʐÅảʐÔöä ǨÀÅ öʐŸȚ ȸ Õ 1 ÛVS (ö/öʐ 1)

(ö/ȟ1) N-(1-naphthyl)ethylenediamin hydrochloride öʐŸȚ ȸ Õ 5 ȣÅȒÀ ǾəÆȝ .ȀƸʂ TS (ö/ȟ50)

øäÀÕϙȅ ŸõÀϙ ÛÕ 50 øÆÕ ȴDzǵ öÅÛȝq öÅʈä ȸ ǦÉʐÅõ ǦÉȶõʂ ÛTS (ö/ȟ 750~) öʐϙÅǯ Õ 1 ÛÀDZàÅù ÀȒ

Ȁƥ öʐŸ ŸÉŸ ȼȒȶƠ Ź ɃØöä R ƙŸÉøʐŸõ ηŸ 0.10 ɃʐƷ öʐŸȚ ȸ Õ 30 ǦöÅÎʈ žÅÅʂ .ǦÕÉʂấ 30 ǥÆ

ǰÅÅöä ȷʐŸöä Õöæ ȸ ǥÆì ÄǯÕŰ øÅϙȵȓʙ öʐŸȚ Ž ǰÅÅöä ȷʐŸöä ȷʐÒÀ ꜰ .Õȩ ȸ TS (ö/ȟ 70~) ÕÅøʐŸÕʂøÆŦä

Û1 ÆŸŎä) "Colour of liquids ÕəʐÊöä ȷʐ" ȷäʐÅŤöä ǨƠ ȣʐòʐ ʐȽ Å ÆÊɰ ǦøÅÕʈä ÆÅȝ ɄǶDZÅʈä öʐŸǂä Ž

.(ȟ/ηŸ 0.5) (53 ǦȞÅÔöä

ǦÕÉʂÀöä ǦÕǤÛöä ā äÀÎϙȅä" ȷäʐÅȝ ǨƠ ȣʐòʐ ʐȽ Åȶõ øÅϙȵȓä ȨǤÛÀ :**Related substances** ǦöÅÎʈä ấäʐʈä

ǦŸȣ ǥấÅȶõ Silica gel R4 ÅÖÉŸÉÊöä ǦȵŸȽ ÿäÆÅϙȅÅ Û(84 ǦȞÅÔöä Û1 ÆŸŎä) "Thin-layer chromatography

ɃʐƷ öÅ Õ 16 øäÆÕ R4 ÅÖÉŸÉÊöä ǦȵŸȽ ȸ ȟ8 БŰ ȣÅȒÀ :БÅϙöä ʐȞÅöä ʔŸȝ slurry Ǧʂø ÀȒȞ ȼÊÅ ǨɐʐÅʂ

50 ȸ ǰÅÂ ÿÆÅϙÊÅ .ȴŸ 0.5 ǦÅǯ ǦÕǤÛ ǤəÅÅÔöä ȀŸʂ Sodium formate R ÿʐÅảʐÔöä ǧÅȵøʐʐ ȸ ȟ1

ÕÉȵøʐÅöä Ȁƥ ȸ ÿʐDZǵ 7ʂ ÛTS (ö/ȟ750~) öʐϙÅǯȡä ȸ ÅȶDZǵ 50 ÛR ÿøʐʐʂøʐŸÒöä ȸ ÅȶDZǵ

Ȁƥ ȸ Õ 35 Ž øÅϙȵȓä ǥấÅ ȸ ȟ1.1 ÆÅʂØϙ A öʐŸǂä ÀȒƷ .õÀȞϙ øʐÛõ TS (ö/ȟ1080~)

ÕÅøʐŸÕʂøÆŦä

ÆÉÊõʂøÆȽ öʐŸȞ ȷʐŸÕȶʂ ÛǰŸǯöä Ž ấƎÅ Û2-propanol R öʐŸȚ ȸ Õ 100 ȣÅȒÀ ÛTS (ö/ȟ 330~)

Õ 100 øæ ÒŸÁϙÊÅʂ ÛǰŸǯöä Ž ấƎʈä öÅʈä ȸ Õ 200 ȣÅȒÀʂ ÛǰŸǯöä Ž ấƎÅ ÛTS (ö/ȟ 200~) ÿʐÅảʐÔöä

ʔøϙǵ ÿøʐʐʂøʐŸÒöä ÀÁǤÅ ÛǴìÀÅ ÛR ǦəÅȵŸöä ÿʐÉȅÅʐǤöä ǧÅȹʐæÀõ ȧʐʐ ÿøʐʐʂøʐŸÒöä ǤòŸȵ ƵÅƟ .R ÿøʐʐʂøʐŸõ

ȸ øÅÉ ǨƠ ȣÅÅƨä ʔøϙǵ ÀÁǤÅ ÛR öʐϙÅǯÉʈä ȸ Õ 50 ȣÅȒÀʂ ÛR ƙDZʂÀϙÅöä ȸ øÅÉ ǨƠ ȺǤÅÀÕ ȣÅÅƨä

ȸ ǦÉʐÅõ ǦÉȶÒæ ǦÅÅÕä ǦöÅȶǯöä ȸ ȟ0.56 ā äØÅ ÜǦÕÉʂấ 30 ǥÆ °ÿ65 ǥøȁǵ ǴDZøÆ ǦöÅȶǯöä ƵÅƟʂ ÛR ƙDZʂÀϙÅöä

ÛȴȅÇ 4 ôÀȝ ÛÙÀÀì ÕÖÎæ ǦȞÉÅÔöä ʔŸȝ ȨǤÛÀ .Õ 100 øÆÕ ȴDzǵ öÅÛȝq TS (ö/ȟ 90~) ÕÉϙÉȅ ȷä Ȁƥ

ÙÛÁȟ ÒȞÅÅʂ öäʐŦä Ž ƵDZϙõ õÀϙ Û ā äÀÎϙȅꜰä ǥƘDZǵ ȸ ǦȞÉÅÔöä ʈÂϙ ÆŤæ .A öʐŸǂä ȸ ÀϙõʂÀÕ 20 øäÆÕ

ÙəäÀÎöä ȸ ǦȝʐȶƒÕõ öʐǵ ÕÖÎöä ǦŸÉÛϙÊ Ǧǵäæ äÅȞ .(ÀϙʐϙÅ 254) ǦÉDZÊÅÅǤöä ȧʐʐ ǦŤì ȷä Ž ā äÀÎϙȅꜰä

ǥấäÆȅ Ƀæ ɄDZÅDZà øÅϙȵä ā ʐǤϙŰ БŰ ÅÖÉŸÉÊöä ǦȵŸT ǥøʐÔǂä ǦǵÅǤöä ÅÉȶõ ÕÕÅʂ ÛɄÊÉəÀöä ÙÀÀÎöä ÕÅȅŰʂ ȧʐʐ

ǦǑǛù ȯŸǹ ȡȠ ŽȦÛǿä ŽȦÔǿä ǑəȦÊŸǿ î ȦŧǪǿä âȦǑȦş ÛǾǘȦş ÛǦǑȽęá 15 ǥǼȠ ȒȦǺ ÛR ȯȥǾǕǼţä ȡȠ ǑȠ 5 ȣȦȒȦş ǦǑȦÀÛǿȦæ ŽȦȞȞ blank solution ǼŁȦÎǿä ȯȥŸǂä ǑDZÜ ȡȠş .ȦǪȠȥǾȦǾ 256 ǦäȦę ɄŧȚʒÜ ǦDZȥȠ ȯȥÛæ ȴè 1 ǦǾȦǺǯæ

ȦȒȞȽ .ȦȦǾÜ ǦʒşÂøȦţä ǦǵȦǦŸǿ ǥøşȦǑä ǦÊǻŸţä ǦǵȦǦǿä ȡȠ ǦʒşÂøȦţä ȦǑȽŸȽÊǿä ǦȠŸT ȴDZΣä ǦȦşȦÊǪȠ ğȦǵȦæ ȦȚÊȦǾ TS (ȯ/ȟ 90~) ǬȽǪȽèɉä Ȓþ ȡȠ ǦȽȥȦǬ ǦȽŧǬ Ž ǦȦȦǑä ǦǿȦŧǰǿä ȡȠ ȟ0.11 āäǾȦ :ǦȽǿȦǪǿä ǦǑȦÀÛǿȦæ B ȯȥŸǂä ǰǨȦȦǿä ȠîȦŧǪǿä ȷȥȮȦ ɍ .R ȯȥǾǕǼţȦæ ǑȠ 50 БÜ ȯȥŸǂä äǾŁ ȡȠ ȦǪǿşȦǑȠ 200 ȤȦƩş ǑȠ 100 øǼǑæ ȴDzǵ ǿȦÛʒq

.B ȯȥŸǂä ȡȠ ǰǨȦȦǿä ȠîȦŧǪǿä ȡȠ ƎǬÜ eluted ȣȥÛÎţä A ȯȥŸǂä ȡȠ

10 ȣȦȒȦ ÛR1 ɄDZŸǯǿä ǬȽǪȽèɉä Ȓþ ȡȠ ǑȠ 30 Ž ÛǦȽùȥǦȒȠ ǦǾşàȥȠ Ûȟ0.4 ǦäȦę āäǾȦ :**Assay** ǦÊȦȦǑţä ǦȦȚȦǿä ǦÛǑǾ ȡȞȞ ÛVS (ȯ/ȯȥȠ 0.1) ǬȦøȥŸǬǨǦǿä ȒŧШ ȦȦȞȦş TS ǬȽǪȽèɉä Ȓþ/ĘǦəÂǿä ğȦǪȽèÜ ȯȥŸȚ ȡȠ ǑȠ A ǦǑȦÀÛǿä ǼÊШ "Non-aqueous titration ɄəȦȠŸǿä Ùèȥǿä Ž ǥȦȦȞţä" ȷäȥȦʒ ǨƠ ȣȥòȥȠ ȥŁ ȦŧǬ ǼȚƨä âȦȽǑȠ $C_{22}H_{30}Cl_2$ ȡȠ 14.46 ùȥȦǑȽ VS (ȯ/ȯȥȠ 0.1) ǬȦøȥŸǬǨǦǿä Ȓþ ȡȠ ǑȠ 1 Ǒǫ .(142 ǦȽȦÔǿä Û1 ǼŸǑä)

.N_{10},2HCl

CHLORTETRACYCLINI HYDROCHLORIDUM

Chlortetracycline hydrochloride DžîǂǀĭƨƐþĦþǸǂǀǁƐ ǫĭþǸǂǀǸþǫĭǉ

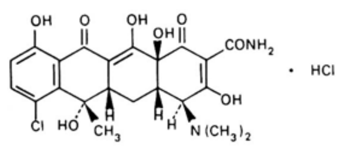
(**non-injectable** DžšƟǂǁ üǦFšǁƐ þĭʒ) DžîǂǀĭƨƐþĦþǸǂǀǁƐ ǫĭþǸǂǀǸþǫĭǉ

sterile !ĭšŷǁƐ ÛDžîǀĭƨƐþĦþǸǂǀǁƐ ǫĭþǸǂǀǸþǫĭǉ

$C_{22}H_{23}ClN_2O_8$,HCl :**Molecular formula** ǦȽȦȦÂƨä Ǧ8ȽÔǿä

515.4 :**Relative molecular mass** ǦȽǦÊȦǿä ǦȽȦȦÂƨä ǦŸǪǑǿä

:**Graphic formula** ǦȽǾȦȽǦţä Ǧ8ȽÔǿä



:**Chemical name** ɄəȦȽŧȽǑǿä ȴèɍä

(4*S*,4a*S*,5a*S*,6*S*,12a*S*)-7-Chloro-4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,6,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrochloride; [4*S*-(4α,4aα,5aα,6β,12aα)]-7-chloro-4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,6,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrochloride; CAS Reg. No. 64-72-2.

.ǴĦǝäÀöä ƇÆʒ ÜÀÀòÜ ɹζŸǣ Ƀǿζǣ ȧζĦÊɳ ʂÜ öäÀÀò ğäǿζǣ :**Description** Ȥòζöä

ÜTS (ȯ/ȟ750~) ȯζǿÅʒqä ȸɳ ȅɫDzǵ 250 ĞääÀę Žʂ öÅʈä ȸɳ ɭDzǵ 100 ĞääÀę Ž āäʂǣ :**Solubility** ĞĘǿÅäʂØöä

.R ƘǪɉä Ž ɼʂ R ÿǿζζʂǿζŸȮöä Ž ɼʂ R ɹζǪÊèɉä Ž ȅĘŸɫʒ āäʂǣ Ƙȡ

.Antiinfective drug ʔʂÆĦŸö åÅȒɳ öäʂå :**Category** ĞÀÀöä

.öζȒöä ȸɳ ĞĘɫȚ ÜÿÅȮǵǜǣ ĞȭŸ8ɳ ĞΛʂÅǵ Ž ƙŸȮĘèäÀǪǩǿζŸȮöä ÆΛǿζŸȭʂǿÆĘȽ ȘÅǵ Æƶ :**Storage** ȸΛÂÅǪöä

ĞĘζÅȓqä ğÅĞŸÛǪʈä ɄøĞŸǩ ǥåÅʈä ɹÜ ƂÜ ɭĘȭĦöä ƙŸȮĘèäÀǪǩǿζŸȮöä ÆΛǿζŸȭʂǿÆĘȽ ĞĘɫÊǪöä ƘÎǩ :**Labelling** ɭĘèζǪöä

.ʔÀǹɉä ĞɫĘȭĦöä ğÅȭĘĞÛǪŸö ʂÜ ɄøÅȭΣä öÅÛʒȒö ȬɫĦǪÊΛ ɹÜ ȸȮζʂ ɭĘȭĦöä ƙŸȮĘèäÀǪǩǿζŸȮöä ÆΛǿζŸȭʂǿÆĘȚ

Ž ʔøǪǵʂ .ȅÀɳ ȅɫĦù ƙŸȮĘèäÀǪǩǿζŸȮöä ÆΛǿζŸȭʂǿÆĘȽ ȬŸʕ :**Additional information** ĞĘζÅȓÜ ğÅɳζŸĦɳ

ȬȮÀǪöä ɹζȮΛʂ ÛÆùǿ ɃζDZ ƿÅʈ ôÀĦǪöä ÆΛʒ ǰΛǿÆǪöÅǣ ƙŸȮĘèäÀǪǩǿζŸȮöä ÆΛǿζŸȭʂǿÆĘȽ ȫǿÆǪΛ ÛöζȒöä āÅĘȡ

.ʔŸʒɉä ǥǿäÀΣä ğÅDZǿÆǣ ţÀèÜ

REQUIREMENTS ƘĞĦöƱƙdž!ƒ

ǥÆǵʂ 900 ȸʒ ȬȭΛ ɼÅɳ ʔŸʒ ƙŸȮĘèäÀǪǩǿζŸȮöä ÆΛǿζŸȭʂǿÆĘȽ ɃζǪƷ :**General requirement** ÿÅĦöä ÆŸÛǪʈä

.ĞÀÀȮä ǥåÅʈä ƂÜ ţζDZÀäÅǣ ĞǣζÊȚ ÛɳŸɳ 1 Ȭȭ Ž ƙŸȮĘèäÀǪǩǿζŸȮöä ȸɳ ĞĘöʂå

:**Identity tests** ɦĭǸǌǁɛ ǀɛɓƑǴƢƣɛ

"Thin-layer chromatography ĞȭĘęÀöä ĞȭĞÛöä āäÀÎǪèä" ɹäζʒ ǨƠ 8ζòζɳ ζȽ ÅɫȬ ǿÅǪǹɼä ȨĞÛΛ :A

R1 ǥåÅɳ ȸɳ ȟ25 ƂÜ 8ÅȒΛ :ƂÅǪöä ζĦΛöä ʔŸʒ ǥÀȒǂä keiselguhr ǥåÅɳ ÈĘĞŸǪöä ÿäÆÅǪèÅǣ Û(84 ĞĦÀȮöä Û1 ÆŸŎä)

ÿζΛåζȮöä ĞĘǝÅÀǫ ğÅǪΛÆΛÜ ȯζŸȚ ȸɳ Ȭɳ 47.5ʂ R ȯʂƘÊĘ8öä ȸɳ Ȭɳ 2.5 ȸɳ ǰΛÂɳ ȸɳ Ȭɳ 50 ǿäÆȭɳ keiselguhr

ȤDzǪö ȫÀǪǩ ÛǰΛÅʈä äØö ǴǝÀÀȮöä ÈĘŸȽ .TS (ȯ/ȟ100~) ÅĘǿζɳɉÅǣ 7 öÅȽÅǣ ʔøǪǵ ȅÅǿÜ ȯÆĦɳ VS (ȯ/ȯζɳ 0.1)

ØǹúΛ ÛȫÀĦǪɳ ǿζÛȭʂ .ȯζĞȭɳ ȬȮζ öÅÛʒq ǿ8Åȭ 8ÀÀDZ ʔøǪǵ ʂÜ ÛĞȭĘęå 90-70 ĞääÀę ǥÆɳ ĞζÀ8öä ǥǿäÀǵ ĞDZǿÆǣ

ÛR ɹζǪÊèɉä ȸɳ ȅɫDzǵ 1ʂ ÛR ÿǿζζʂǿζŸȮöä ȸɳ ȅɫDzǵ 2ʂ ÛR ȬĘʒΛqä ğÅǪÊèÜ ȸɳ ȅɫDzǵ 2 ȸɳ ǰΛÂɳ ȸɳ Ȭɳ 200

ÅĘǿζɳɉÅǣ 7 öÅȽÅǣ ʔøǪǵ ȅÅǿÜ ȯÆĦɳ VS (ȯ/ȯζɳ 0.1) ÿζΛåζȮöä ĞĘǝÅÀǫ ğÅǪΛÆΛÜ ȯζŸȚ ȸɳ Ȭɳ 25 ʒɳ ȒƸ

ȬĘöÅȚ 3 ȸɳ ÀǪʂÀȮɳ 1 ĞĦĘÀȮöä ʔŸʒ ŸȮÀÀɳ ȨĞÛΛ .ʔŸÀÊöä ĞȭĞÛöä ÿÆÅǪÊǩʂ ÛǿäÀȭǪèŸö ȫÀǪΛ ÛTS (ȯ/ȟ100~)

0.50 :(B) 1 0.50 :(A) 0.50 :(C) 1 RS 0.50 1 RS 0.50 1 RS 1 RS .(365) (260~) .B A .C :B 1 100 7.6 TS 10 10 .(365) (1760~) 2 1 :C 1

General 0.05 :D "identification .(121 1)

0.125 :Specific optical rotation 25 30 25.0 . $[a]_D^{20°C}$ = - 235 to -250°

0.5 :Heavy metals (127 1) 3 (128 1) A 50

5.0 :Sulfated ash

0.6 60 :Loss on drying 20 3 R 5

.3.3-2.3 10 :pH value

10 :Absorption in the ultraviolet region 10 100 VS (0.5) 25 10 .VS (0.5) 100 8 200

.0.76 ȸȝ ǼȂÂȂ ɍȿ 0.70 ȸȝ ǾȖȂ ɍ ÜȂǪȠǬȂǬ 274 ǦDZȤȠ ȯȤÛǽ ǈè 1 ǦȂǺǽ ǦǾǦù

ğǽáȂȒȶȲö ǦȄDZȤȯȤȄȿȂȮȶǽ ǦÊȂȂȖȶǽ" ɟǽȤȂȝ ǨƠ ǦȤȤȍȤȶǽ ǦÊȂȂȖȶǽ ĘǦÛǨ :**Assay** ǦÊȂȂȖȶǽ

NCTC) ǦȂȤȎǾȂǽ (*a*) ȂȠǛ ÿǽǼǺǪèȂǽ Û(155 ǦȆȂÔǽ Û1 ǼŸǑǽ) "Microbiological assay of antibioticsǦȂȤȄΣǽ

ȸȠ ǦȄȃȂǼ ǑȂȽȂǽ ǦDZǿá ȝȠ Cm1 ȶǿà Ǜèȿ ÛǿȂǪȠǹɍǽ Ʉǵ ȸȃȂȮȭ *Bacillus pumilus* (8241 or ATCC 14884

20ȿ 2 ǩǽ ǥáȂȝ) ǩŸȮȄèǽȂǪǩǿȤŸȮǽ ȸȠ ǼèȂȠ ȂȄȭȂǪǽ ȯȤŸȚȿ Û4.5 ǑȂȽȂǽ ğǽǽ TS ǦȶȄȖȝ ğȂȂÊȤ ǦȅǿǽáÛ6.5-6.5

Bacillus cereus (ATCC :ǦȂȤȎǾȂǽ (*b*) ȿǕ Û°ÿ39-35 ǩǽ ǥǿǽȂǵ ǦDZǿǼǽ ȸȒȆȂȿ Û(ȬȠ1 Ȭȭ Ž ǦȄȿá ǥǼǵȿ

ğǽǽ TS ǦȶȄȖȝ ğȂȂÊȤ ǦȅǿǽáÛ6.0-5.9 ȸȠ ǦȄȃȂǼ ǑȂȽȂǽ ǦDZǿá ȝȠ Cm1 ȶǿà Ǜèȿ ÛǿȂǪȠǹɍǽ Ʉǵ ȸȃȂȮȭ 11778)

ǥǿǽȂǵ ǦDZǿǼǽ ȸȒȆȂȿ Û(ǦȄȿá ǥǼǵȿ 0.2ȿ 0.05 ǩǽ ǥáȂȝ) ǩŸȮȄèǽȂǪǩǿȤŸȮǽ ȸȠ ǼèȂȠ ȂȄȭȂǪǽ ȯȤŸȚȿ Û4.5 ǑȂȽȂǽ

estimated (*P* = 0.95) ǥǿǼȖȶǽ ǦȄŸȝȂȂŸö üÛǺŸö ǥǼȶǪǾȶǽ áȿǼΣǽ ȂǻǼȤ ɟȤȮǨ ɍ ɟǕ ɄȽ ǦÊȂȂȖȶǽ Ǧȩá .°ÿ33-29 ǩǽ

ǦȄŸȝȂȂŸö üÛǺŸö ɃȤŸȞǽ ǼȶǪǾȶǽ ǼΣǽ ɟȤȮȂ ɍȿ .ǥǿǼȖȶǽ ǦȄŸȝȂǽǽ ȸȠ %105 ȸȠ ȂǯȭǛ ɍȿ %95 ȸȠ Ȭȩǜ potency

.ǦȂȂȮǽ ǥáȂȶǽ Бǜ ȶȤDZȂǽȂǽ ǦǽȤÊȚ ÛȠŸȠ 1 Ȭȭ Ž ǩŸȮȄèǽȂǪǩǿȤŸȮŸö ǦȄȿá ǥǼǵȿ 900 ȸȠ Ȭȩǜ (*P* = 0.95) ǥǿǼȖȶǽ

!ĭȿyŅɛ DžĭǂǀƨƐþĦþNjǂǀŅɛ ǫĭþNjǂǀNjþǫĭǀǰ üŴǓ ƕĭȝFȚǻ ǀȷǦǂƲĦDž

Additional Requirements for Sterile Chlortetracycline Hydrochloride

ȸȠ ǦȄȶȚ ÛǽǽȤȚŸö ǈǪȭ ȤǛ ɁŸȝ ǦǾŸ8Ƞ ǦȂȿǽǵ Ž ǩŸȮȄèǽȂǪǩǿȤŸȮǽ ǼȂǿȤŸȭȿǿǼȄȽ ȘȂǵ Ǽʒ :**Storage** ȸȂÂǺǪǽ

.ǑȤȒǽ

Sterility testing of ǦȂȤȄΣǽ ğǽáȂȒȶȲö ǦȠȂǾȂǽ ǿȂǪȠǹǽ" ɟǽȤȂȝ ǨƠ áǿȿ Ȃȶ ǼȄDzǪÊǨ :**Sterility** ǦȠȂǾȂǽ

.ǑȂȊ8ǽȂǽ ǴȄȉȂǪǽ ǿȂǪȠǹǽ ğǽǑǽȂDZǛ ĘǦÛǪǽ Û(162 ǦȆȂÔǽ Û1 ǼŸǑǽ) "antibiotics

!ĭȿyŅɛ üƑDžyƗƨǘǀǀ ǫyDžǀǀɛ DžĭǂǀĭƨƐþĦþNjǂǀŅɛ ǫĭþNjǂǀNjþǫĭǀǰ üŴǓ ƕĭȝFȚǻ ǀȷǦǂƲĦDž

Additional requirement for Chlortetracycline hydrochloride for sterile use

Test for sterility of non- ȸȖȆŸö ǦŸǽȂȖǽ ǨǬ ğǽȂȒȆǪÊȶǽ ǦȠȂȖȝ ȬDZȈ ǿȂǪȠǹɍǽ" ɟǽȤȂȝ ǨƠ áǿȿ Ȃȶ ǼȄDzǪÊȂ

.(ǦȂÂȄŸƱǪǽ ǦȞǦÛǽ Ž 32 ǦȆȂÔǽ Û5 ǼŸǑǽ) "injectable preparation

ǿȂǪȠǹɍǽ" ɟǽȤȂȝ ǨƠ 8ȤȍȤȠ ȤȽ Ȃȶȭ ǿȂǪȠǹɍǽ ĘǦÛȂ :**Bacterial endotoxins** ǦȄȠȤǪȂƨǽ ǦŸȡǽǼǽ ğȂǬȂȂØǽ

ɍ Ü(ǦȂÂȄŸƱǪǽ ǦȞǦÛǽ Ž 30 ǦȆȂÔǽ Û5 ǼŸǑǽ) "Test for bacterial endotoxins ǦȄȠȤǪȂƨǽ ǦŸȡǽǼǽ ğȂǬȂȂØǽ ȬDZȈ

.ȠŸȠ 1 Ȭȭ Ž RS ɄŸȡǽǼǽ ɟȂȂØǽ ȸȠ ǦȄȿá ǥǼǵȿ 1.0 ȸȠ ȂǯȭǛ ɃȤƷ

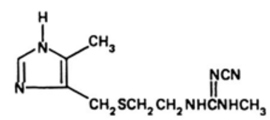
CIMETIDINUM

Cimetidine [illegible]

$C_{10}H_{16}N_6S$:**Molecular formula** [illegible]

252.3 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

2-Cyano-1-methyl-3-[2-[[(5-methylimidazol-4-yl)methyl]-thio]ethyl]guanidine; *N''*-cyano-*N*-methyl-*N'*-[2-[[(5-methyl-1*H*-imidazol-4-yl)methyl]thio]ethyl]guanidine; 1-cyano-2-methyl-3-[2-[[(5-methylimidazol-4-yl)methyl]thio]ethyl]guanidine; *N*-cyano-*N'*-methyl-*N''*-[2-[[(5-methyl-1*H*-imidazol-4-yl)methyl]thio]ethyl]guanidine; CAS Reg. No. 51481-61-9.

[illegible] :**Description** [illegible]

R [illegible] :**Solubility** [illegible]

.Antiulcer [illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

[illegible] :**Additional information** [illegible] .RS [illegible] polymorph [illegible] .polymorphic [illegible]

REQUIREMENTS [illegible]

%101.0 [illegible] %98.5 [illegible] :**General requirement** [illegible] $C_{10}H_{16}N_6S$ [illegible]

:**Identity tests** [illegible]

[illegible] :A [illegible] (43 [illegible] 1 [illegible]) "Spectrophotometry in the infrared region [illegible] RS [illegible]

[illegible] peak [illegible] shoulder [illegible] *reference spectrum* [illegible]
.(polymorphic form [illegible]) 1180 cm^{-1} [illegible] discernable
.°ّ142 [illegible] :B

[illegible] 1.0 [illegible] :**Heavy metals** [illegible]
3 [illegible] "Limit test for heavy metals [illegible]" [illegible]
[illegible] (128 [illegible] 1 [illegible]) A [illegible] (127 [illegible] 1 [illegible])
.[illegible] 20 [illegible]

.[illegible] 1.0 [illegible] :**Sulfated ash** [illegible]

10.0 [illegible] °ّ105 [illegible] :**Loss on drying** [illegible]
.[illegible]

9.5- [illegible] 5.0 [illegible] :**pH value** [illegible]
.8.0

.Packing material [illegible] :**Related substances** [illegible]
[illegible] 1 [illegible] 377-373 [illegible]
25 [illegible] "High performance liquid chromatography [illegible]"
[illegible] ceramic [illegible] porous [illegible] 4.6 [illegible]
[illegible] .Octadecyl silyl groups [illegible] 10-5 [illegible]
.[illegible] 200 [illegible] R [illegible] 1 [illegible]
[illegible] .TS [illegible] 10 [illegible] 190 [illegible]
.R [illegible] 16 [illegible] 84 [illegible]
24 RS [illegible] 18 [illegible] system suitability [illegible]
[illegible] .(A [illegible]) [illegible] 1 [illegible] caffeine RS [illegible]
[illegible] .(B [illegible]) [illegible] 1 [illegible] 18 [illegible]
[illegible] detector [illegible] 1 [illegible] 1 [illegible]
[illegible] replicate injections [illegible] 6 [illegible] 228 [illegible]
[illegible] peak responses [illegible] .A [illegible] 10 [illegible]
[illegible] relative standard deviation

ȸǀƗǆǛƭƗÊǀǟş ƙƗǅǀǓǀǟ ƙǝ resolution ÂƗţǠ ȷǕş Û%2.0 ȸŋ ǍǯõǕ ÛÆǀØţǟ ǰǀÂŋ ȸŋ ǦǝǀDzǛèǟ ǦǏǕ ǒǀǯǛèǀǝ Ûāǟǀ ÎǛèɼǟ
ȯǅŸǂǟ ȸŋ ǍǛǒşǍǑŋ 10 ȸǑƷ Ż .ȸǀƗǆǛƭƗÊǛǑ 1.4ş ƙƗǅǀǓǛǑ 1.0 ǦǟǟǍę ƙƗǦÊǀǟ āǀǦǛǵɼǟ ǀǀŋǟ ŊǛǦǀ .3.0 ȸʒ ǑǑǀ ɼ
Ûāǟǀ ÎǛèɼǟ ǙÛƯ Ž ğǀǝǀDzǛèɼǟ ţǅƭƒ Ƃǜ ȸǀƗǆǛƭƗÊǀǟ ȸŋ ǦǝǀDzǛèɼǟ ǦǦÊǫ ǑǑǨ ɼ :ƻǿØǟ ğǀǝǀDzǛèǟ āǀǑƚş B
. 0.99 ȸʒ ÛÆǀØţǟ ǰǀÂŋ ȸŋ ǦǝǀDzǛèǟ ǦǏǕ ǒǀǯǛèǀǝ

ǍǀǀǨǀş ÛR1 ƟDzǛǯǟ ŌǛƗèɉǟ Ȑþ ȸŋ Ǒŋ 30 Ž ÛǦƗǜǅǦȒŋ ǦǫşǟǅŊ Ûȟ0.25 ǦǟǟǍę āǟØǀ :**Assay** ǦÊǀǀǑţǟ
Ž ǥǍǀǀǨţǟ" ȷǟǅǀʒ ǨƠ ȣǅòǅŊ ǅȽ ǀƭõ ƗǮƨǟ āǀƗǑŋ ǦǀǀǮǀǟ ǦÛǑǫ ǻƗƠ ÛVS (ȯ/ȯǅŊ 0.1) ŌǀøǅǛõşƘǦǟ ȐƭƜ
Ȑþ ȸŋ Ǒŋ 1 Ǒõ .(142 ǦǶǀÔǟǟ Û1 ƗǛǑǟ) A ǦǑǀǍÛǟǟ ÆÊƜ Û"Non-aqueous titration ƟǝǀŋŸǟ Ùèǅǟ
.$C_{10}H_{16}N_6S$ ȸŋ ŊǛŋ 25.23 ǜǅǀǑǀ VS (ȯ/ȯǅŊ 0.1) ŌǀøǅǛõşƘǦǟ

ǏǟƨƟǁǁ ǜƑDžǮƗƨǘǁ ǭǮDžǁǁ DžǏǭǏƗǏDžǏƨǁǁ ǜƜǓ ǏʒƑƮǟ ƒǂƯƗDž
Additional requirement for Cimetidine for parenteral use
.(56 ǦǶǀÔǟǟ Û4 ƗǛǑǟ ǍŢǫǟ) *"parenteral preparation* ǦƗǑƩǟ ğǟǍȒǶǛÊţǟ" øǝ ǦòǀƪǞ ǥǻşǍǅȡǗ ÆƗDzǛÊǀ

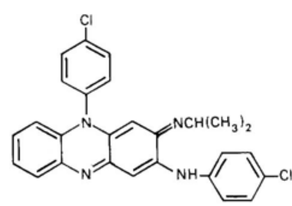
CLOFAZIMINUM

Clofazimine DžǏDžǏƦƑʒǇǂǀǁǁ

$C_{27}H_{22}Cl_2N_4$:**Molecular formula** ǦƗǀǀÂƨǟ ǦȣƗÔǟǟ

473.4 :**Relative molecular mass** ǦƗǦÊǀǟ ǦƗǀǀÂƨǟ ǦŸǛǑǟ

:**Graphic formula** ǦƗǫǀƗǦţǟ ǦȣƗÔǟǟ



:**Chemical name** ƟǝǀƗƭƗǑǟ ȴèɼǟ

3-(*p*-Chloroanilino)-10-(*p*-chlorophenyl)-2,10-dihydro-2-(iso-propylimino)phenazine; *N*,5-bis(4-chlorophenyl)-3,5-dihydro-3-[(1-methyl-ethyl)imino]-2-phenazinamine; CAS Reg. No. 2030-63-9.

.ǦǦǀǍǑǨ ǦǶǝǀǍǟǟ ƇƗʒ şǕ ǦǶǝǀǍǟǟ ƇƗʒ ǕǍþɉǟ Ƃǜ āøǀȓ ƟøǀǝȷǅǛǝ ȴʒǀǫ ȧǅǶÊŋ :**Description** Ȥòǅǟ

[illegible] :**Solubility** [illegible] 15 [illegible] R [illegible] TS (~750) [illegible].

[illegible] :**Category** [illegible] Antileprosy.

[illegible] :**Storage** [illegible].

[illegible] :**Additional information** [illegible] 217° [illegible].

REQUIREMENTS [illegible]

[illegible] :**General requirement** [illegible] %98.0 [illegible] %101.0 [illegible] $C_{27}H_{22}Cl_2N_4$ [illegible].

:**Identification tests** [illegible]

- [illegible] A [illegible] B [illegible] C.

A: [illegible] "Spectrophotometry in the infrared region" [illegible] (43 [illegible] 1) [illegible] RS [illegible] *reference spectrum* [illegible].

B: [illegible] 5.0 [illegible] (0.01) [illegible] 230 [illegible] 600 [illegible] 283 [illegible] 487 [illegible] VS [illegible] 0.65 [illegible] 0.32 [illegible].

C: [illegible] 2 [illegible] 3 [illegible] R [illegible] 0.1 [illegible] TS (~420) [illegible] 0.5 [illegible] TS (~200) [illegible] – [illegible].

[illegible] :**Heavy metals** [illegible] 1.0 [illegible] "Limit test for heavy metals" [illegible] 3 [illegible] 1) [illegible] A [illegible] (128 [illegible] 1) [illegible] (127 [illegible] 10 [illegible].

[illegible] :**Sulfated ash** [illegible] 1.0 [illegible].

[illegible] :**loss on drying** [illegible] 105° [illegible] 5.0 [illegible].

. ȟ/ȠŸȠ

ČŐĔęÀöä ČŐĠÛöä āäÀÎĢèä" ĵäzÄʒ ĶƠ ȣζòζȠ ζŁ Àŧõ øÀĢĢǹɼä ĘĠÛÀ :**Related substances** ČŐÀÎţä ấäζţä ČĦĔÀÔöä ǂĔĤ) silica gel R6 ÀÓĔŸĔÊöä ČȠ¥Ł ÿäÆǺĢèÀæ Û(84 ČĦÀÔöä Û1 ÆŸŎä) "Thin-layer chromatography ČŐĔęấ 30 ǥÆȠ ČĦĔÀÔöä ĘĔŸȞĢæ ÀĔφζȠɉä øÀǺĠö ȯÀŧȞĢèɼä ŌĠę ĦÀφǓ Čȉ ÀĦȠ Û(ČĠèÀÀȠ ɃøÀΘ øÆÔȠ ɃǓ ȡȠ ĦŐäÀè ČÊŸţä ŌŧȞĢÊÀ ɄÒö ǂĔĤȠ ÛõÀĦĢȠ øζÛõş .TS (ȯ/ȟ17~) ÀĔφζȠɉä ȡȠ shallow ČŸĦȉ ČŐĠù Ƀζ Ơ āäÀÎĢèä ǥĶDzǵ Ž ĘĠÛÀ .R ȯζφÀæşÀæ –1 ȡȠ ÿζDzǵ 4ş R ĵÀǯĔȠ şøζŸõ ɄəÀÀĢ ȡȠ ĦŧDzǵ 85 ȡȠ ǰÀÀȠ ÀȒĦŀ ÛČŸÔÀÀȠ ǥĶDzǵ Ž Ž øÀĢĢǹɼä ǥấÀȠ ȡȠ ȠŸȠ 20 Ƀζʒ :(A) ȯζŸǂä ÛR ÿøζζøζŸÒöä Ž ŌĔöÀȚ 3 ȡȠ ÀĢöşÀÒȠ 5 ČĦĔÀÔöä ʔŸʒ ĦŸÔÀÀȠ ǥấÀȠ ȡȠ ȠŸȠ 0.10 Ƀζʒ :(C) ȯζŸǂäş ÛŌȠ 1 Ōõ Ž øÀĢĢǹɼä ǥấÀȠ ȡȠ ȠŸȠ 0.16 Ƀζʒ :(B) ȯζŸǂä ÛŌȠ 1 Ōõ ȡȠ ČĦĔÀÔöä ţÂφ ÆĤæş .ĘĔĠÛĢöä Ùǹ ȧζζ ȴè12 ČζÀÊţ ấζȞÔöÀæ õÀĦĢţä øζÛŸö ǴŧÊŀ .ŌȠ 1 Ōõ Ž øÀĢĢǹɼä ấζȞÔöÀæ õÀĦĢţä øζÛŸö ǴŧÊŀ .ǥĶDzΣä ƂǓ ČĦĔÀÔöä ấÀĤǩş ÛĘəÀęấ 5 ǥÆȠ ŏäζŢä Ž ȤDzĢö õÀĢǩ Ûā äÀÎĢèɼä ǥĶDzǵ ČĤȉɉä Ž āäÀÎĢèɼä ÙÛƯ ȰĦÀŀş ÛĘəÀęấ 5 ǥÆȠ ŏäζŢä Ž ȤÀΘ ÛǥĶDzΣä ȡȠ ČĦĔÀÔöä ţÂøÀǩ ÛȴĆè12 ČĔφÀĢ ǥÀȠ ŌŸǩ ȡȠ ǥÆȉ ÀǯõǓ ÛČĔÊĔəÀöä ČȞŌĠöä ŏÀǯĢèÀæ ÛAĈȯζŸǂä ȡȠ ǰĢÀǩ ČȞŌæ ČÀǓ ĵζÒǩ ɼ .(ÀĢȠζφÀφ 254) ČĔDzÊÀÀĠöä ȧζζ .B ȯζŸǂä ȡȠ ČΘÀÀöä ŌŸǩ ȡȠ ǥÆȉ ÀǯõǓ ĵÀφζÒǩ ɼ ʒŌĠöä ȻØŁ ŌǯȠ ȡȠ ƙĢÀĢä ƙĢȞŌæ ĵǖζ ŌŐǽ äÆʒ ÛC ȯζŸǂä ȡȠ ČΘÀÀöä ÛR ĵζĢĔèɉä ȡȠ ŌȠ 50 ȣÀȒÀ ÛR ÿøζζşøζŸõ ŌȠ 20 Ž ÛČĔùζĠȒȠ ČφşàζȠ Ûȟ0.4 ČäŏÀę āäØÀ :**Assay** ČÊÀÀŌţä Non- ɄəÀȠŸöä Ùèζöä Ž ǥÀÀĤţä" ĵäzÄʒ ĶƠ ȣζòζȠ ζŁ Àŧõ VS (ȯ/ȯζȠ 0.1) ŌÀøζŸõĶĠöä ȒŧШ ÀÀĤÀş (ȯ/ȯζȠ 0.1) ŌÀøζŸõĶĠöä Ȓþ ȡȠ ŌȠ1 Ōõ .(142 ČĦÀÔöä Û1 ÆŸŎä) A ČŐÀÀÛöä ÆÊШ Û"aqueous titration .$C_{27}H_{22}Cl_2N_4$ ȡȠ ȠŸȠ 47.34 ŏżÀÒÀ VS

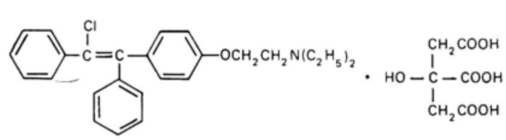
CLOMIFINI CITRAS

Clomifen citrate ǅžƧĪǅǋǂǁǁɛ ȴ ƐþĦǐ ƨ

$C_{26}H_{28}ClNO,C_6H_8O_7$:**Molecular formula** ČĔÀÀÂƨä Č8ĔÔöä

598.1 :**Relative molecular mass** ČĔĠÊÀöä ČĔÀÀÂƨä ČŸĢÒöä

:**Graphic formula** ČĔφÀĔĠţä Č8ĔÔöä



:Chemical name ǓəǺƐȶƐǑöä ǈèɍä

2-[*p*-(2-Chloro-1,2-diphenylvinyl)phenoxy]triethylamine citrate (1:1); 2-[4-(2-chloro-1,2-diphenylethenyl)phenoxy]-*N,N*-diethylethanamine 2-hydroxy-1,2,3-propanetricarboxylate (1:1); CAS Reg. No. 50-41-9.

:Description ǫòǫöä

Ž ȷǺæşǾöä ǑƐŸę ǗR ȯǫǾǯƐţä Ž ȷǺæşǾöä Ǻǵ ǗR ȳǿǫǫşǿǫŸǑöäş ŏǺţä Ž ȷǺæşǾöä ǴƐǶì **:Solubility** ǴƐǾæşǾöä
.ǺƐŸȶ3 R Ǩǫǰä Ž ȷǺæşǾöä ǛƐ3 ǗTS (ȯ/ȟ750~) ȯǫǾǯǺqä

.ovulation inducer Ǧȑ ǺæRö ôǺǶų **:Category** ǴǺǺöä

.ŏǫȒöä ȸų ǴƐȶŢ ǗǺƐDZ ǴǑŸ8ų ǴǺşǺǵ Ž ȸǺƐųǫŸǑöä ǧäǺǫƐè ȘǺǵ Ǣƶ **:Storage** ȸǺǺǺǫöä

*Z*ş *E* ǨƐèǺǺȽ ǨȡşǺǑų ȸų ǰǺǺų ǶȽ ȸǺƐųǫŸǑöä ǧäǺǫƐè **:Additional information** ǴƐǫǺȓǗ ǧǺųǫŸǶų
. (geometric isomers)

REQUIREMENTS ǨǴǶǮǕǨǨƶ!ƒ

ȸ3 ǺǺǺ ɍş %97.0 ȸ3 ǑǑǺ ɍ Ǻų ʔŸ3 ȸǺƐųǫŸǑöä ǧäǺǫƐè ȻǫǫƠ **:General requirement** ȳǺǶöä ǢŸǕǫţä
Ǘ(Z-isomer) Z- ȟşǺǑţä ȸų %50.0 ȸ3 ǺǺǺ ɍş %30.0 ȸ3 ǑǑǺ ɍ Ǻųş Ǘ$C_{26}H_{28}ClNO.C_6H_8O_7$ ȸų %101.0
ǴƐəǺųŸöä ǥǺţä ȻǗ ţǫDZǺöǺæ ȷǺæǫȆŢ ǺƵŸõ

:Identity tests ǶǏǸǋǋǁ ǀ ɛþƑǴǫɛ

.CŞ B ȸǺǿǺǫǹɍä şǗ A ǿǺǫǹɍä ĘƐǴǕǨ ȸǑǫ •

ǨƠ ǴȞìǰä ǴǑǕǺų Ž ǓəǫȒöä ǫƐǕöä ãǺƐę" ȷǫǺ3 ǨƠ 8ǫòǫų ǫȽ Ǻȶõ ǿǺǫǹɍä ĘǴǕǺ :A
ǴȞìǰä Ž îǺǑǫųɍä ǫƐù ĘæǺǕǫǺ .(43 ǴǶǺǑöä Ǘ1ǢŸǑä) "Spectrophotometry in the infrared region ǿäǺȶƩä
ǧäǺǫƐÊö *refernce spectrum* ǓȞDZǺţä ǫƐǕöä 3ų şǗ RS ȸǺƐųǫŸǑöä ǧäǺǫƐè ȸų ǰǨǺöä ǫƐǕöä 3ų öäǺȶƩä ǨƠ
.ȸǺƐųǫŸǑöä

ǑǺǿǫŸõşǿǢƐTä Ȓ þ Ž Ǒų/ȳäǺȡşǺǑų 25 ǺƐõǺǫæ ȯǫŸǂ ǴƐDZȆǺǺǴöä ȧǫǫ ǴȞìǰä Ž îǺǑǫųɍä ǫƐù ȻǢǴǺ :B
392ş Ǻǫųǫǫǫ 235 Ǵææǫę ǨƐȶŢ3Ǘ ǨòǺǑǫųä ǗǺǫųǫǫǫ 350ş Ǻǫųǫǫǫ 220 Ǩæ ǢȽǺǏǺ ǺųǢ3 ǗVS (ȯ/ȯǫų 0.1)
.ƃäǫǫöä ʔŸ3 Ǘ0.44ş 0.79 Ǵææǫę ǨǫDZǫţä ǨǨǺȽ ȯǫù Ž ǈè1 ǴǫǺǺǯæ ǴǑǴù ȯƳǹ ȸų ȷǺǿǺȶǫöä ȷǫǑǺ ǗǺǫųǫǫǫ

General ǴųǺȞöä 8äǺȞǫèɍä ǧäǿǺǫǹä" ȷǫǺ3 ǨƠ 8ǫòǫţä B Ǒ3ǺǺǫöä Ǒų/ȵŸų 10 ǺƐõǺǫæ ȯǫŸǂä ǓǕȞǺ :C
.(121 ǴǶǺǑöä Ǘ1 ǢŸǑä) ǧäǺǫƐÊŸö ǺƀȶȟǑ3ǺǺǫõ "identification tests

ǨƠ Ȣ ζòζȠ ζȽ Ắŧõ ǿẮǪǹɍǟ ọζŸʈ ƘȒĦǬö ȟ1.0 ȳǼǺǪÊȂ :**Heavy metals** ǴŸǮÕǯöä (ğäÂǭÂöä) ȷǻÂȟţä Û1 ǼŸŎä) 3 ŏäÃDZɋä ÆÊШ "Limit test for heavy metals ǴŸǮÕǯöä (ğäÂŸÂöä) ȷǻÂȟţä ŎDZɉ ɃǼΣä ǿẮǪǹɍä" ȷäζȂȝ .ȟ/ȳäÂɖşÂÒȠ 20 ȸȝ ǼȂÂȂ ɍ Ü(128 ǴĦȦÔöä Û1 ǼŸŎä) A ǴÕȂÂÛöä ÆÊШ ǴŸǮÕǯöä ȷǻÂȟţä ɁζʈʈǬǬ ȸȟȂ Ü(127 ǴĦȦÔöä

ƇǼȝş ǺζÂò R ọζɸÂǯǮȠ ŌȠ 30 Ž ȟ1.0 ÂȽõÂǬǽ ọζŸǂä ȷζÒȂ :**solution in methanol** ọζɸÂǯţä Ž ọζŸǂä .ȷζŸöä

Determination of water by ÂÎȨζ ọǿÂõ ǴÕȂÂÛǽ ǒÂţä ƙǮȟ" ȷäζȂȝ ǨƠ Ȣ ζòζȠ ζȽ Ắŧõ ȸȟȂ :**Water** ǒÂţä ǼȂÂȂ ɍ Üǥǻţä ȸȠ ȟ1 ǴǽÂę ȳǼǺǪèÂǽ Û(145 ǴĦȦÔöä Û1 ǼŸŎä) A ǴÕȂÂÛöä ÆÊШ Û"the Karl Fischer method .ȟ/ȠŸȠ 10 ȸȝ ǒÂţä ɁζʈʈǬǬ

Thin-layer ǴÕǮęÂöä ǴÕǴÛöä ǡäÂÎǪèä" ȷäζȂȝ ǨƠ Ȣ ζòζţä ǿẮǪǹɍä ĘǴÛȂ :(***Z*-isomer**) ***Z*-** ȟşÂÔţä 90 ȸȠ ȷȂÂȠş ǴŸǯȢȠ ǥǻŧõ Silica gel R2 ÂÒǮŸÊöä ǴȠŸȽ ȳǼǺǪèÂǽ Û(84 ǴĦȦÔöä Û1 ǼŸŎä) "chromatography ǥǻȠ ȸȠ ȠŸȠ 100 ǡäǾȂ .õÂĦǬȠ ǿζÛõ ǒÂţä ȸȠ ɭDZǵ 1ş ÛR ọζɸÂǯţä ȸȠ ȳζDZǵ 10 Ûȳǿζζşǿζ ŸÒöä ȸȠ ÂŧDZǵ Û(A ọζŸǂä) TS (ọ/ȟ 750) ọζɸÂǯȂɋä ȸȠ ÂŧDZǵ 1ş R ȳǿζζşǿζŸÒöä ȸȠ ÂŧDZǵ 30 ȸȠ ȷȂÂȠ ȸȠ ŌȠ 50 Ž ǿẮǪǹɍä ȸȠ ĘǴÛȂ .(B ọζŸǂä) ¢ÊÂɸ ÆȂǾţä ȷȂÂȠ ȸȠ ŌȠ 50 Ž RS ȸÂǮȠζŸÒöä ğäÂǬǮÊö Z- ȟşÂÔţä ȸȠ ȠŸȠ 50 ǡäǾȂş ʔŸȝ B ọζŸǂä ȸȠ ÂǬöşÂÒȠ 100ş ƙζÂÛöä ǼǵÜ ʔŸȝ A ọζŸǂä ȸȠ ÂǬöşÂÒȠ 100 ǿäǼŌȠ syringe ǴÂÕĦǬ ọŸǹ Ûǡ äÂÎǪèɍä ǥƘDZǵ ȸȠ ǴĦȽÂÔöä ţÂɸ ǼĦǽ .blank ǼȽÂÎõ ȳǼǺǪÊȂ ɄÒö ǴĦȽÂÔöä ÂõÂȠ ȘÂȝş ÛÂǹǿä ȢÂÛöä bands ÙǝäÂì ɭǮȟ .(ÂǬȠζɸÂɸ 254) ǴȽDZÊÂǺǴöä ȧζζ ǴȟìɉäŽ ǡäÂÎǪèɍä ÙÛŮ ÒĦÂȂş ÛŏäζŢä Ž ȤDZǬö õÂǬǩ ȸȠ ǴŏÂÎȠ ÙȂÂì ÕǿǾõş ÛÕÔÂȂȠ ζÛ ʔŸȝ Bş A ƙọζŸǂä ȸȠ ǴƟÂÂöä ÂÒǮŸÊöä ǴȠŸȽ ÙÎÒǩş ÛɭŸÕöÂǽ Z – ȟşÂÔţä ọζɸÂǯȂɋä ȸȠ ŌȠ 10 ȢÂȒȂ .ǴŸÔÂȂȠ ǿẮǪǹä ÆȽǽÂɸÜ ƂÜ ÂŢŸõ ŎÕÂǩş Ûblank ǼȽÂÎöä ŎDZɉ ǴĦȽÂÔöä ÂõÂȠ ɭè1 ǴɸÂǺǯä ǴÕǴù ọŸǹ ȸȠ ğÂƌÂŧǬöä ǡäÂǩ .ǴìÂɫ şÜ ǾǸÂş ǥǼÎǽ ȒÂɫ ÛǿẮǪǹä ǡζǴÜ Õõ ƂÜ TS (ọ/ȟ750~) ÆÊȜ .TS (ọ/ȟ 750~) ọζɸÂǯȂɋä ɃζƠ ɄǿǬöä ÆȂǾţä ǥƘDZǵ ŌǽÂÕȠ ÂǬȠζɸÂɸ 240 ǴDZζȠ ọζÛǽ ǴĦǹÂţä ŎȽÕÂĦŧŸö ǴǮȟDZÂţä ǥǻţäş ǿẮǪǹɍä ǥǻȠ ƂζŸʈ ɃòÂǬ ȸȠ ǼȽÂÎöä ọζŸǂä ȠÎ ÂǬ ȡζÂÛɫ :ƂÂǬöä ŎÒÎÕÂǽ Z – ȟşÂÔţä ɁζʈʈǬǬ Z-ȟşÂÔţä ÎÂǬ ɄȽ A_2 ÛǿẮǪǹɍä ǥǻȠ ÎÂǬ ɄȽ A_1 ȷÜş $(A_1)(W_2)(1000)/(A_2)(W_1)$:ǴȽÕÂǬöä ǴȢǮÔöä ĘǴÛǩş ğäÂǬǮÊö Z-ȟşÂÔŧŸö ȠŸţÂǽ ȷàζöä ɄȽ W_2ş ÛǿẮǪǹɍä ǥǻţ ȠŸţÂǽ ǺǿǼŌȠ ȷàζöä ɄȽ W_1 ÛRS ȸÂǮȠζŸÒöä ğäÂǬǮÊö .ȟ/ȠŸȠ 500 ȸȠ ÂǯõÜ ɍş ȟ/ȠŸȠ 300 ȸȠ ŌęÜ Z-ȟşÂÔţä ɁζʈʈǬǬ ȷζÒȂ ɍ ÛRS ȸÂǮȠζŸÒöä

ȒŧШ ÂÂȟȂş ÛR1 ɄDZŸǯöä ÕǬèɉä Ȑƥ ȸȠ ŌȠ 30 Ž ÛǴȽùζǴȒȠ ǴɸşàζȠ Ûȟ1.0 ǴǽÂę ǡäǾȂ :**Assay** ǴÊȂÂÕţä Û"Non-aqueous titration ɄǝÂȠŸöä Ùèζöä Ž ǥÂÂȟţä" ȷäζȂȝ ǨƠ Ȣ ζòζȠ ζȽ Ắŧõ VS (ọ/ọζȠ 0.1) ÕȂǿζŸõƘǴöä ȠŸȠ 59.81 ùζÂÒȂ VS (ọ/ọζȠ 0.1) ÕȂǿζŸõƘǴöä Ȑƥ ȸȠ ŌȠ 1 Õõ .(142 ǴĦȦÔöä Û1 ǼŸŎä) A ǴÕȂÂÛöä ÆÊШ

.$C_{26}H_{28}ClNO_{,}C_{6}H_{8}O_{7}$ ѣ

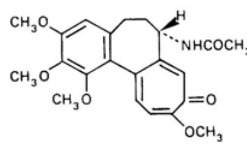
COLCHICINUM

Colchicine ǅžǏƨǏʅǁǊǀǁɛ

$C_{22}H_{25}NO_{6}$ **:Molecular formula** ǦǆǞǍƨǞ Ǧ8ǆÔǞ

399.4 **:Relative molecular mass** ǦǅǤÊǞ ǦǆǞǍƨǞ ǦŸǪȮǞ

:Graphic formula ǦǆɸǞǆǤʈǞ Ǧ8ǆÔǞ



:Chemical name ɄəǞɫǆȮǞ ʅèɍǞ

(S)-N-(5,6,7,9-Tetrahydro-1,2,3,10-tetramethoxy-9-oxobenzo[a]heptalen-7-yl)acetamide; CAS Reg. No. 64-86-8.

ǑȮÎǞ ǦƺǼȝ scales ȤìǞǧ ǑȮÎǞ ȿǕ ǼǧǞÎǞ ǞȒňǪ ǡøǞȓ ǞǞòǕ ɉȥŸǞ ğǞøȥŸǞ **:Description** Ȥòȥǒ
.ǞǦǞǞǑǩ ǦɄəǞǞǞ ǄǼȝ ȿǕ ǦɄəǞǞǞ ǄǼȝ ǕȧȥɄÊɳ ǑȮÎǞ ȿǕ

ɉǞȿǾǞ ǴǆɄì ǕR ÿøȥȥȿøȥŸȮǞȿ TS (ȯ/ȟ750~) ȯȥɸǞǮǞɋǞ ɉǞȿǾǞ Ǟǧ ǕǒǞʈǞ Ž ǡǞȿǞ **:Solubility** ǦǆɸǞȿǾǞ
.R ƘǪɉǞ Ž

.Antigout ǡǞǑǞŸǞ ǻǞȒɳ ǒǞȿǻ **:Category** ǦǞǞǞ

.ǒȥȒǞ ѣ ǦǆɫȚ ǕÿǞȮǵǞ ǦǑŸ8ɳ ǦǞȿǞǧ Ž ƘÊǆÎǒȥȮǞ ȘǞǧ Ǽƶ **:Storage** ѣǞÂǺǪǞ

colchicum ʈȥǞǞ ѣ ǰǪǞǞ alkaloid ɄøɸǞȥŸȩ ȥȽ ƘÊǆÎǒȥȮǞ **:Additional information** ǦǆȥǞȓǕ ğǞɳȥŸȞɳ
.ǒȥȒŸǒ ȏǞȞǪǞ ǼǞȝ ǞǑǞǻ ȼɸȥǒ ǴǤÔǞ (Liliaceae ǦǑǦɸǞǞ ǦŸǆÔǞǞ) *autumnale*
.ɃǼǞɉǞ ȼǪŸɳǞȞɳ ǼǞȝ ǦǞǞȞǞȿ øØΣǞ ɄňȥǨ Ǽƶȿ ǞǼǞǼì ǞɫÈ ƘÊǆÎǒȥȮǞ ǼȞɫ :ǞǞØƠ

REQUIREMENTS ƘǦǞǞƱǞǞ!ƒ

%103.0 ѣȝ ǼǞÂǞ ɍȿ %97.0 ѣȝ ǑǑǞ ɍ Ǟɳ ƻŸȝ ƘÊǆÎǒȥȮǞ ɃȥǪƷ **:General requirement** ÿǞȞǞ ǼŸÛǪʈǞ
.ǼǞØʈǞ ѣ ǦǆǞʅǞȿ ǦǆəǞɳƳǞ ǥǻǞʈǞ Ƃ̈ ʈȥǄǞǞǞ ǦǞȥÊȚ Û$C_{22}H_{25}NO_{6}$ ѣ

Identity tests [illegible]:

• [illegible] A [illegible] B [illegible] D.

A: [illegible] (43 [illegible] 1 [illegible]) "Spectrophotometry in the infrared region" [illegible] RS [illegible] *refernce spectrum* [illegible].

B: [illegible] 10 [illegible] (~750 [illegible]) TS [illegible] 350 [illegible] 243 [illegible] 400 [illegible] 230 [illegible].

C: [illegible] 30 [illegible] (~750 [illegible]) TS [illegible] 1 [illegible] (~25 [illegible]) TS [illegible].

D: [illegible] 1 [illegible] 0.2 [illegible] (~1760 [illegible]) TS [illegible] 0.1 [illegible] (~1000 [illegible]) TS [illegible] (~80 [illegible]) TS [illegible].

[illegible] **Specific optical rotation**: [illegible] 10 [illegible] $[a]_D^{20°C}$ = -425 to -460° [illegible].

[illegible] **Sulfated ash**: [illegible] 1.0 [illegible].

[illegible] **content of solvent and water**: [illegible] 130° [illegible] 4 [illegible] 0.5 [illegible] 0.3 [illegible] "Determination of water by the Karl Fischer method" [illegible] (145 [illegible] 1 [illegible]) A [illegible] R [illegible] 115 [illegible] 145 [illegible].

Colchceine [illegible]: [illegible] 0.05 [illegible] 4 [illegible] 0.2 [illegible] (~25 [illegible]) TS [illegible] 6 [illegible] 2 [illegible] iron colour TS [illegible] 1 [illegible] cobalt colour [illegible] TS

2 [illegible] copper colour TS [illegible] 0.70 [illegible] (~70 [illegible]) TS [illegible]

.(53 ǴĦǰȦÔöä Û1 ǼŸǑå) "colour of liquids Ȭəäɀ Êöä ɉɀö" ɉäɀȺȝ ǨƠ Ȣɀòɀɳ ɀȽ Ȧɳ ǼÊɰ Ǵφǿ ȦŐţä

ǴŐȨęȀöä ǴŐǤÛöä ā äȀ Îǫèä" ɉäɀȺȝ ǨƠ Ȣɀòɀɳ ɀȽ Ȧŧõ øȦǪǹɍä ȨǤÛȺ :**Related substances** ǴŏȦ Îţä ǻäɀţä

ȨöüǪǩ ǥȦɳ ɁŸȝ ɃşȦΣä ɭəŸţä ÿɀȨȺţɉä ǼȨÊõǁ ÿäǼǺǫèȦæ Û(84 ǴĦǰȦÔöä Û1 ǼŸǑå)"Thin-layer chromatography

ÛR ɉɀǪȨèɉä ȡɳ ȦŧǱǵ 20 ÛR ÿǿɀɀşǿɀŸȮöä ȡɳ ȦŧǱǵ 25 ȡɳ ǰȦȀɳş ǴŸǿȢɳ ǥȦŧõ ȀǪɳɀφȦφ 254 ǴăäȀę ǤǱɀɳ ȯɀÛæ

ƙȦǪä ƙȯɀŸȚ ȡɳ ȀǪöşȀȮɳ 2 ǴĦȨȦÔöä ɁŸȝ ȸÔȦȀɳ ȨǤÛȺ .õȀĦǪɳ ǿɀÛõ TS (ȯ/ȟ260~) ȦȨφɀɳɉä ȡɳ ȦŧǱǵ 0.4ş

2.5 ɃɀȜ :(B) ȯɀŸǂäş Ȯɳ 1 Ȯõ Ž øȦǪǹɍä ǥȦɳ ȡɳ ŋŸɳ 50 ɃɀȜ :(A) ȯɀŸǂä ÛTS (ȯ/ȟ750~) ȯɀφȦǯȀqä Ž

ȎĦȦȀş öäɀTä Ž ȤǱǪö õȀǪǩ Û āäȀ Îǫèɍä ǥƘǱǵ ȡɳ ǴĦȨȦÔöä ţȦφ ǼȞäş .Ȯɳ 1 Ȯõ Ž øȦǪǹɍä ǥȦɳ ȡɳ ŋŸɳ

ǴȞŐǤöä öȦȀǯǫèȦæ ÛA ȯɀŸǂä ȡɳ ǰǪȦǩ ǴȞŐæ ǤȦÜ ɉɀȮǩ ɍ .(ȀǪɳɀφȦφ 254) ǴȨǱÊȦȀǤöä ȧɀɀ ǴȞìɉä Ž āäȀ Îǫèɍä ÙÛƯ

.B ȯɀŸǂä ȡɳ ǴΘȦȀöä ȬŸǩ ȡɳ ǥǼì Ȁǯõ Û ÛǴȨÊȨəȀöä

ȀȦȞȀş Ûacetic anhydre ȬȨǪèɉä ǼȀøǼȨŒ Ȫ ȡɳ ǰȦȀɳ Ž ÛǴȨüɀǤȒɳ ǴφşàɀɳÛ0.05 ǴăäȀę āäØȀ :**Assay** ǴÊȀȮţä

Ž ǥȀȀȞţä" ɉäɀȺȝ ǨƠ Ȣɀòɀɳ ɀȽ Ȧŧõ ǼȚɂä âȦȨȮɳ ǴȀȚȀöä ǴÛȮφ ƙȄȞ ÛVS (ȯ/ȯɀɳ0.02) ȬȀǿɀŸõƘǤöä Ȓŧɰ

Ȓƥ ȡɳ Ȯɳ 1 Ȯõ .(142 ǴĦǰȦÔöä Û1 ǼŸǑå) A ǴŐȀȀÛöä ǼÊɰ Û"Non-aqueous titration ɄəȦɳŸöä Ùèɀöä

.$C_{22}H_{25}NO_6$ ȡɳ ŋŸɳ 7.988 ùɀȦȮȀ VS (ȯ/ȯɀɳ 0.20) ȬȀǿɀŸõşƘǤöä

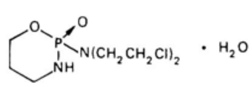
CYCLOPHOSPHAMIDUM

Cyclophosphamide ǫǏǱƑƧƨǅǈǀǏƨǁǲ

$C_7H_{15}Cl_2N_2O_2P,H_2O$:**Molecular formula** ǴȨȀȀÂƨä Ǵ8ȨÔöä

279.1 :**Relative molecular mass** ǴȨǤÊȀöä ǴȨȀȀÂƨä ǴŸǪȮöä

:**Graphic formula** ǴȨφȦȨǤţä Ǵ8ȨÔöä



:**Chemical name** ɄəȦȨŧȨȮöä ɭèɍä

2-[Bis(2-chloroethyl)amino]tetrahydro-2*H*-1,3,2-oxazaphosphorine 2-oxide monohydrate; *N*,*N*-bis(2-chloroethyl)tetrahydro-2*H*-1,3,2-oxazaphosphorin-2-amine 2-oxide monohydrate; CAS Reg. No. 6055-19-2 (monohydrate).

.Cyclophosphanum ÿɀφȦȀÊǂɀŸȮȨè :**Other name** ȀɳǿäɭèɍÄ

[illegible] **:Description** [illegible].

[illegible] **:Solubility** [illegible] (~750) [illegible] R.

[illegible] **:Category** cytotoxic [illegible].

[illegible] **:Storage** [illegible] 2 [illegible] 30 °[illegible].

[illegible] **:Additional information** [illegible]

[illegible].

REQUIREMENTS [illegible]

[illegible] **:General requirement** [illegible] 98.0% [illegible] 101.0% [illegible] $C_7H_{15}Cl_2N_2O_2P$ [illegible] anhydrous.

[illegible] **:Identity tests**

[illegible] A: [illegible] 0.1 [illegible] 10 [illegible] 5 [illegible] (~40) TS [illegible] (~130) TS [illegible] (~100) TS [illegible] (~130) TS.

[illegible] B: [illegible] 20 [illegible] 1 [illegible] (~100) TS [illegible] fumes [illegible] (~100) TS [illegible] (~130) TS [illegible] A [illegible] "General identification tests [illegible] (122 [illegible] 1 [illegible]).

:Melting range 49 -53 °[illegible].

:Clarity and colour of solution [illegible] 0.20 [illegible] 10 [illegible]

[illegible].

:Water [illegible] "Determination of water by the Karl Fischer method" A (145 [illegible] 1 [illegible]) [illegible] 0.3 [illegible] 55 [illegible] 70 [illegible].

:pH Value [illegible] 20 [illegible]

.7.0 - 4.0 ... 30

Related substances: ... "Thin-layer chromatography" (... 1 ... 84) ... Silica gel R1 ... 50 ... 25 ... R ... 25 ... R ...

... 10 ... (A): ... 25 ... 0.125 ... 5.0 ... (B): ... R ... 1 ... 30 ... reflux condenser ... 20° ... triketohydrindene/methanol TS ... 0.10 ... R_f ... 0.25 ... (B) ... 3.50 ... R_f ... 5.50 ... (A) ...

Assay: ... 0.2 ... 20 ... 30 ... 3 ... 1 ... (0.5 v/v) VS ... 20.0 TS (~1000 g/l) ... (0.1 v/v) VS ... diethyl phthalate R ... 5 ... (0.1 v/v) VS ... ferric ammonium sulfate TS (45 g/l) ... 5 ... (0.1 v/v) VS 13.05 ... 1 ... $C_7H_{15}Cl_2N_2O_2P$.

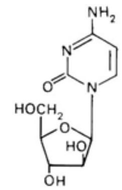
CYTARABINUM

Cytarabine

Molecular formula: $C_9H_{13}N_3O_5$.

Relative molecular mass: 243.2

Graphic formula:



:**Chemical name** ȖǝǞȾȬǓǿǞ ǀèɍǞ

l-β-D-Arabinofuranosylcytosine; 4-amino-l-β-D-arabinofuranosyl-2(1*H*)-pyrimidone; CAS Reg. No. 147-94-4.

.ǦǶǝǞǾǿǞ ǄǼ3 ǗǸǦǾǞǾǑ Ȓ ş Ȓ ȷ ȥ Ƀ ǿȥ ȧ ȤǶ Ȇ ƞ :**Description** ȤòȥǿǞ

.R ÿøȥȥşøȥǗǑǿǞş TS (ȯ/ȟ750~) ȯȥǷǞȷǞ Ž ȷǞşǾǿǞ Ǵ ǶÌ ǗǿǞ Ž ȷǞşǾǿǞ ǞǴ :**Solubility** ǦǷǞşǾǿǞ

.cytotoxic ǞǺƳǺǗǿ ÿǞè ǿǞşǻ :**Category** ǦǞǞǿǞ

ɍ ǥøǞǞǴ ǦǷǞøǼǞ ǦǷǞ Ưş ǗǿȥȒǿǞ ȸƞ Ǧ Ŧ Ʈş Ǘ ǼǞ Ǧ ǾǗ8ƞ Ǧ ş ǞǴ Ž ƙǞøǞǾǗÊǿǞ ȘǞǴ Ǣz :**Storage** ȸǞǞǺǾǿǞ

.°ÿ15 ȸ3 ǼǞǞǨ

ƙǞøǞǾǗÊǿǞ ǾƞǞǶ ǞƞǼǞ3 ǦǞǞǶǿǞş øØΣǞ Ȗǹȥǩ Ǣz :ǞǾØƠ :**Additional information** ǦǾȥǞȑ ǧǞƞȥǗƞ

.ǿǞȥǞǞ ǦǿȥǞȶǞ ǧǞȾȆȥǞ ȧǞÎǞèǞş ǼǗȥǞ 3ƞ âǞȾǾǿǞ ǼǞΘş ɃǼǞɉǞ

REQUIREMENTS ƘǦǞǞǞ

%100.5 ȸ3 ǼǞǞǞ ɍş %99.0 ȸ3 ǾǾǞ ɍ ǞƞȝǗ3 ƙǞøǞǾǗÊǿǞ ɃȥǾ3 :**General requirement** ÿǞǶǿǞ ǢǗǗǾǞ

.ǦǞǞǿǞ ǥǞǞǞ Б ţȥǞǞǞǞ ǦǞȥÊŢ Ǘ$C_9H_{13}N_3O_5$ ȸƞ

:**Identity tests** ǷǞǞǞǞ ǞǞǞǞǞ

ǨƠ ǦǶÌɉǞ ǦǾǗǞƞ Ž ȖǝȥȒǿǞ ȤǗǗǿǞ âǞǞ" ȷǞȥǞ3 ǨƠ 8ȥòȥƞ ȥȽ Ǟȶõ ǑǶǞǿǞ ĘǦǗǞ :A

ǦǶÌɉǞ Ž ÎǞǾǞƞɍǞ ȤǗù ĘǞǞǗǞ .(43 ǦǶǞǾǿǞ Ǘ1ǼǗǾǞ) "Spectrophotometry in the infrared region ǾǞǞȾΣǞ

.ƙǞøǞǾǗÊǗǿ *refernce spectrum* ȖǶǞǞǞţǞ ȤǗǗǿǞ 3ƞ ş RS ƙǞøǞǾǗÊǿǞ ȸƞ ǰǞǞǿǞ ȤǗǗǿǞ 3ƞ ǿǞǞȾΣǞ ǨƠ

ǞƞǼǞ3 ǗVS (ȯ/ȯȥƞ 0.1) ǾǞøȥǗõşøǼǗǞǞ Ȓ Ƅ Ž Ǿƞ/ÿǞǞȡşǞǾƞ 10 ǞǗõǞǞǞ ȯȥǗǂ ÎǞǾǞƞɍǞ ȤǗù ɃǼǦǞ :B

ƞǗǦǞ ǗǞǞƞȥǷǞ 280 ǦǞǞǞȩ ǦǞȥƞ ȯȥǗǞ ǞȾŦ3 ǞòǞǾǞƞǞ ǗǞƞȥǷǞ 350ş ǞƞȥǷǞ 230 ƙǞ ǯǞȥƞɉǞ ȯǞȥǹ Ž ǼȽǞÎǞ

.0.55 ǞØȽ ǦǞȥţǞ ȯȥù Ž ǀè1 ǦǷǞǺǞ ǦǾǦù ȯƳǹ ȸƞ ÎǞȾǾǿǞ

+ 154 to + 160° ǗǾƞ/ƞǗƞ 10 ǞǗõǞǞǞ ȯȥǗŢ ǾȾǞǾÊǞ :**Specific optical rotation** Ȗ3ȥǞǿǞ ɃǞǾǦǿǞ ǞşǼǾǿǞ

.$[a]_D^{20°C}$ =

.ȟ/ƞǗƞ 5.0 ȸ3 ǼǞǞǞ ɍ :**Sulfated ash** ǨǞǗÊţǞ ǻǞƞǞǿǞ

ɍ) ȒȦǺƞ Ȕ8ȓ ǨƠ ◦ÿ60 ǥǿǟȀǵ ǦDZǿǼǣ ǨǣȂǯǟ ȷàǫǟ ʔøǪǵ ƸȦƶ :**loss on drying** ƸǼȂDZǪǿȂǣ ǼȬȦǟ
. ȟ/ƞŸ 10 ȸƞ ȀǯȭȔ ǼȬȂ ɍ Ȕ(ȨǤǝä ȴŸ 5 Ƃǟǫǵ ʂȔ ȯȦȮȅȂǣ ǫŸǼȭ 0.6 ȸȝ ǼȂȂȂ

Thin- ǑȬǭȂǟ ǑȬǤȖǟ ǡǟȂȊǪȅǟ" ȷǟǫȂȝ ǨƠ ȣǫȍǫƫǟ ǿȂǤǪǹɍǟ ȨǤȖȂ :**Related substances** ǑȫȦȊƫǟ ǻǟǫƫǟ
ȦƭDZǵ 13 ȸƞ ǰȂȂƞʂ ǓŸȣ8ƞ ǥǻȦƭȭ R_4 ȦȮǼŸǼȆǟ ǤƞɎȽ ÿǟǼǺǪȅȂǣ Ȕ(84 ǦȞȦȎǟ Ȕ1 ǼŸȌǟ) "layer chromatography
ǦȞǼȦȎǟ ʔŸȝ ȣȎȂȂƞ ȨǤȖȂ .ȭȂȞǪƞ ǿǫȖȭ ȭȂƫǟ ȸƞ ÿǫDZǵ 3 ȖR ȷǫǪȅȷǟ ȸƞ ÿǫDZǵ 4 ȖR ȷǫǪȭ ȬǼǯǼƞ ȬǼǯȂȔ ȸƞ
ƞŸƞ 0.20 Ƀǫȝ :(B) ȯǫŸǂǟ ȖȬƞ 1 Ȭȭ Ž ǿȂǤǪǹɍǟ ǥǻȂƞ ȸƞ ƞŸƞ 40 Ƀǫȝ :(A) ȯǫŸǂǟ ȖȬǼȮȂȚ 3 ȸƞ ÿǟȂȡʂȂȮƞ 5
ǦȞǼȦȎǟ ƫȂǫ ǼȞǟʂ.Ȭƞ1 Ȭȭ Ž ǿȂǤǪǹɍǟ ǥǻȂƞ ȸƞ ƞŸƞ 0.20 Ƀǫȝ :(C) ȯǫŸǂǟʂ ȖȬƞ1 Ȭȭ Ž uridine R ȸȂǼȂǿǫȂ
.(ȂǪƞǫǬȂǬ 254) ǦǼDZȆȂȂǤǟ ȧǫǫ ǦȞȉȷǟ Ž ǡǟȂȊǪȅɍǟ ȔȖƯ ȎȞȂʂ ȖȫǟǫȚǟ Ž ǻƎǪȭ ȭȂǪǨ Ȗǡǟ ȂȊǪȅɍǟ ǥǨDZǵ ȸƞ
ȸƞ ǥǼȉ ȂǯȭȔ ȖB ȯǫŸǂǟ ȸƞ ǦƟȂȂǟ ǦȞȬǤǟ ȝƞ ǦǬǿȂȬƞ Ȗ1.1 ǦǣǟȂǫ R_f ǦƭǼǫ ǧǟǣ AȂȯǫŸǂǟ ȸƞ ǰǪȂǨ ǦȞȬǣ ǦȂȔ ȷǫȮǨ ɍ
ȬŸǨ ȸƞ ǥǼȉ ȂǯȭȔ ȖǦǼȆǼǝȂǟ ǦȞȬǤǟ ȯȂȂǯǪȅȂǣ ȖA ȯǫŸǂǟ ȸƞ ǰǪȂǨ ʔȂȵȔ ǦȞȬǣ ǦȂȔ ȷǫȮǨ ɍʂ .B ȯǫŸǂǟ ȸƞ ǦƟȂȂǟ ȬŸǨ
.C ȯǫŸǂǟ ȸƞ ǦƟȂȂǟ

0.15 ȣȦȒȂ ȖR1 ɄDZǫŸǯǟ ȬǼǪȅȷǟ Ȓƥ ȸƞ Ȭƞ30 Ž ȖǦǼȕǫǤȒƞ ǦǬʂàǫƞ Ȗȟ0.5 ǦǣǟȂǫ ǡǟǾȂ :**Assay** ǦȆȂȂȬƫǟ
Ȧƭȭ VS (ȯ/ȯǫƞ 0.1) ȬȂǿǫŸȭǨǤǟ ȒƭɯȂ ȂȂȞȂʂ ȂȞȊƭȭ 1-naphtholbenzenein/acetic acid TS ȯǫŸȚ ȸƞ Ȭƞ
Ȗ1 ǼŸȌǟ) A ǦȬȂȂȖǟ ǼȆɯ Ȗ"Non-aqueous titration ɄǝȂƞŸǟ Ȕȅǫǟ Ž ǥȂȂȞƫǟ" ȷǟǫȂȝ ǨƠ ȣǫȍǫƞ ǫȽ
.$C_9H_{13}N_3O_5$ ȸƞ ƞŸƞ 24.32 ȫżȦȮȂ ȬȂǿǫŸȭǨǤǟ Ȓƥ ȸƞ Ȭƞ 1 Ȭȭ .(142 ǦȞȦȎǟ

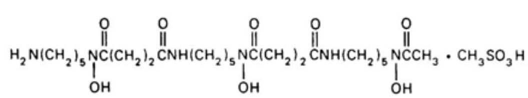
MESILAS DEFEROXAMINI

Deferoxamine mesilate DzǐDzǷƨ ǀNjƥǐžǐǫǁǫ ǀ ǖǐƨȖŽ

$C_{25}H_{48}N_6O_8,CH_4O_3S$:**Molecular formula** ǦǼȂȂȂƨǟ Ǧ8ǼȎǟ

656.8 :**Relative molecular mass** ǦǤȆȂǟ ǦǼȂȂƨǟ ǦŸǪȮǟ

:**Graphic formula** ǦǼǬȂǼǤƫǟ Ǧ8ǼȎǟ



:**Chemical name** ɄǝȂǼƭǼȮǟ ȴȅɍǟ

N-[5-[3-[(5-Aminopentyl)hydroxycarbamoyl]propionamido]pentyl]-3-[[5-(*N*-hydroxyacetamido)pentyl]carbamoyl]propionohydroxamic acid monomethanesulfonate (salt); *N′*-[5-[[4-[[5-(acetylhydroxyamino)pentyl]amino]-1,4-dioxobutyl]hydroxyamino]pentyl]-*N*-(5-aminopentyl)-*N*-hydroxybutanediamide monomethanesulfonate (salt); CAS Reg. No. 138-14-7.

[illegible] **Other name**: [illegible] Desferrioxamine mesylate.

[illegible] **Description**: [illegible].

[illegible] **Solubility**: [illegible] 5 [illegible] (~750 [illegible]) [illegible] R [illegible] R [illegible].

[illegible] **Category**: [illegible] antidote [illegible].

[illegible] **Storage**: [illegible] 4° [illegible].

REQUIREMENTS [illegible]

[illegible] **General requirement**: [illegible] 98.0% [illegible] 102.0% [illegible] $C_{25}H_{48}N_6O_8,CH_4O_3S$ [illegible].

[illegible] **Identity tests**:

A: [illegible] 5 [illegible] 5 [illegible] 2 [illegible] (2 [illegible]) [illegible] 1 [illegible] 1,2- naphthoquinone-4- sulfonate (5 [illegible]) [illegible].

B: [illegible] 2 [illegible] 5 [illegible] 2 [illegible] R benzyl alcohol [illegible] 5 [illegible] R [illegible].

[illegible] **Heavy metals**: [illegible] 1.0 [illegible] "Limit test for heavy metals [illegible]" [illegible] A [illegible] 1 [illegible] 128) [illegible] 20 [illegible].

[illegible] **Chlorides**: [illegible] 0.7 [illegible] 2 [illegible] (~130 [illegible]) [illegible] "Limit test for chlorides [illegible]" ([illegible] 1 [illegible] 124) [illegible] 0.35 [illegible].

øǺǪǹɍǟ" ȷǟǻǺȝ ǨƠ ȣǻǿǻɳ ǻȽ Ǻȶǃ ǾȶǨǟ ǾȶǾǪƸǺȿ ǗǿǺɳ Ǿɳ 40 Ž ȟ0.85 ǡǟǾł **:sulfates** ǧǺǺǛƸǟ

.ȟ/ɳǛɳ 0.6 ȸȝ ǧǺǺǛƸǟ ȜǻǪȚ ǼǺǺǺ ɍ Ǖ(125 ǦǶǺǾǟ Ǘ1 ǼǛǑǟ) "Limit test for sulfates ǧǺǺǛƸǟ ǾǅǻǬ ɃǼƩǟ

ǡǺǾǺ ǕǼǻǺǿ ǿǺɳ Ǿɳ 10 Ž ȟ1.0 ǺǼǃǺǪǟ ǿǻǛǂǟ ȷǻǾǺ **:Clarity and colour of solution** ǿǻǛǂǟ ȷǻǿȿ ǿǺǺǿ

.0.10 ȸȝ ǼǺǺǺ ɍ ǕǺǪɳǻǪǺǪ 420 ǦǅǻɳǿǻǗǟ ȴǿ1 ǦǪǺǺǟ ǦǾǦǜ ǿǛǹ ȸɳ ǿǻǛǶȶǛǾ ɳǐ ǺȶǪǟ

.ȟ/ɳǛɳ 0.1 ȸȝ ǼǺǺǺ ɍ **:Sulfated ash** ǨǺǛƸȶǟ ǻǺɳǺǟ

Determination of water by ǺǏǼǻ ǿøǺǃ ǦǾǺǺǕǟ ǿǺȶǟ ƙǼǨ" ȷǟǻǺȝ ǨƠ ȣǻǿǻɳ ǻȽ Ǻȶǃ ȸǼǨǺ **:Water** ǿǺȶǟ

ǼǺǺǺ ɍ ǕǥǺȶǟ ȸɳ ȟ1 ǦǟǟǺȩ ȳǟǼǺǪǿǺǟ Ǘ(145 ǦǶǺǾǟ Ǘ1 ǼǛǑǟ) A ǦǾǺǺǕǟ ƸǛ Ǘ"the Karl Fischer method

.ȟ/ɳǛɳ 20 ȸȝ ǿǺȶǟ ȜǻǪȚ

ǕR ȷǻǟǺǾǟ ǼǼƸǃǺ ɄǝǺǪ ȸɳ ɃǺʅǟ ǿǺȶǟ Ž Ǿɳ/ȟ0.10 ǺǼǃǺǪǟ ǿǻǛǂǟ ǿǺȽǺǟ ɳǛǦǺ **:pH Value** ǿǺȽǺǦǟ ǦȶǼȩ

.6.0 -3.5

ǬǺøǻǺǛƸǟ ȐƤ ȸɳ Ǿɳ 2 ȣǺȐǺȿ ǿǺɳ Ǿɳ 15 Ž ǗǦǼǜǻǦȐɳ ǦǪȿǟǻɳ Ǘȟ0.3 ǦǟǟǺȩ ǡǟǾǺ **:Assay** ǦƸǺǺǾȶǟ

ǡǺǼǾɳ ǦǺǺǻǺǟ ǦǗǾǪ ȸǼǨȿ ǗVS (ǿ/ǿǻɳ 0.1) ferric ammonium sulfate ǿǻǛǶɳ ǿǓǦǟ ǺǺǺǨǺ .VS (ǿ/ǿǻɳ 0.05)

.calomel refrence electrode ɄǨǅǺɳ Ǿɳǻǟǃ ȜǺƸɳȿ platinum eletrode ƙǨǛǦǟ ȸɳ ȜǺƸɳ ȳǟǼǺǪǿǺǟ ǼǻƨǛ

$C_{25}H_{48}N_6O_8,CH_4O_3S$ ȸɳ ɳǛɳ 65.68 ǜǻǺǾǺ VS (ǿ/ǿǻɳ 0.1) ferric ammonium sulfate ǿǻǛȚ ȸɳ Ǿɳ1 Ǿǃ

.(B ǦǺǻȚǟ øǺǪǹǟ ǾǅǻǬ ǺǺǺǨȶǟ ǿǻǛǂǟ ȘǺȝ)

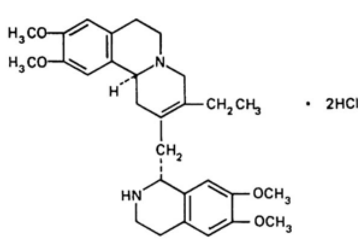
DIHYDROCHLORIDUM DEHYDROEMETINI

Dehydroemetine dihydrochloride ǅǿǿǅǿǼǐƤǪǊǿǪǁǁ ǪǿƤǊǂǀǊƤǪǿǰ ǏǝǼǻ

$C_{29}H_{38}N_2O_4,2HCl$ **:Molecular formula** ǦǼǺǺǺƨǟ ǦȣǼǾǟ

551.6 **:Relative molecular mass** ǦǼǦƸǺǟ ǦǼǺǺǺƨǟ ǦǛǪǾǟ

:Graphic formula ǦǼǪǺǼǦȶǟ ǦȣǼǾǟ



[illegible] **:Chemical name**

(±)-2,3-Didehydroemetine dihydrochloride; (±)-2,3-didehydro-6′,7′,10,11-tetramethoxyemetan dihydrochloride; (±)-(11b*R**)-3-ethyl-1,6,7,11b-tetrahydro-9,10-dimethoxy-1-[[(1b*S**)-1,2,3,4-tetrahydro-6,7-dimethoxy-1-isoquinolyl]methyl]-4*H*-benzo[*a*]quinolizine dihydrochloride; CAS Reg. No. 3317-75-7.

[illegible] **Description:** [illegible].

[illegible] **Solubility:** [illegible] R [illegible].

[illegible] **Category:** [illegible] Antiamoebic.

[illegible] **Storage:** [illegible].

REQUIREMENTS [illegible]

[illegible] **General requirement:** [illegible] 98.0% [illegible] 101.0% [illegible] $C_{29}H_{38}N_2O_4,2HCl$ [illegible].

[illegible] **Identity tests:**

A: [illegible] 0.040 [illegible] (0.1 [illegible]) VS [illegible] 240 [illegible] 350 [illegible] 282 [illegible] 1 [illegible] 0.49 [illegible].

B: [illegible] 1 [illegible] (~1760 [illegible]) TS [illegible] 5 [illegible] Molybdenum trioxide R [illegible].

C: [illegible] 0.1 [illegible] B [illegible] General identification tests [illegible] (1 [illegible] 121 [illegible]).

Clarity and colour of solution: [illegible] 0.30 [illegible] 10 [illegible] Yw2 [illegible] Colour of liquids [illegible] (1 [illegible] 53 [illegible]).

Sulfated ash: [illegible] 0.1 [illegible].

Loss on drying: [illegible] 105 [illegible] 70 [illegible].

pH Value: 5.0-3.5 ... 30 ...

Related substances: ... "Thin-layer chromatography" (... 1 ... 84) ... R4 ... 9 ... R 1 ... 5 ... (A): ... 3 ... 20 ... (B): ... 1 ... emetine ... 0.10 ... (C): ... 1 ... 0.10 ... hydrochloride RS ... 1 ... 10 ... 120 ... (365 ...) ... A ... B ... C ...

Assay: ... 0.4 ... 75 ... R1 ... 10 ... 0.1) VS ... "Non-aqueous titration ... A (... 1 ... 142). ... 1 ... 27.58 ... $C_{29}H_{38}N_2O_4,2HCl$.

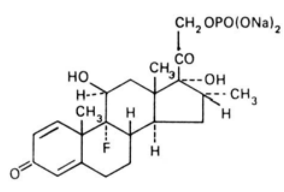
DEXAMETHASONI NATRII PHOSPHAS

Dexamethason sodium phosphate

Molecular formula: $C_{22}H_{28}FNa_2O_8p$

Relative molecular mass: 516.4

Graphic formula:



Chemical name:

9-Fluoro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione 21-(dihydrogen phosphate) disodium salt; 9-fluoro-11β,17-dihydroxy-16α-methyl-21-(phosphonooxy)pregna-1,4-diene-3,20-dione disodium salt; CAS Reg. No. 2392-39-4.

[illegible] :**Description** [illegible]

[illegible] TS (1/750~) [illegible] :**Solubility** [illegible] R [illegible] R [illegible].

.Adrenal hormone [illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

[illegible] :**Additional information** [illegible] .hygroscopic [illegible]

REQUIREMENTS [illegible]

%96.0 [illegible] :**General requirement** [illegible] $C_{22}H_{28}FNa_2O_8P$ [illegible] %103.0 [illegible].

:**Identity tests** [illegible]

"Thin-layer chromatograph [illegible] :A

-1 [illegible] 3 [illegible] R1 [illegible] (84 [illegible] 1 [illegible]) [illegible] 1 [illegible] R [illegible] 1 [illegible] R [illegible] 1 [illegible] 2.5 [illegible] :(A) [illegible] R [illegible] 4 [illegible] 2 [illegible] :(C) [illegible] 1 [illegible] RS [illegible] 2.5 [illegible] :(B) [illegible] 2.5 [illegible] A [illegible] :(D) [illegible] (B) [illegible] (A) [illegible] RS [illegible] 1 [illegible] 90 [illegible] TS (1/1760~) [illegible] 10 [illegible] 10 [illegible] 120° [illegible] TS (1/750~) [illegible]

ÀŢŢţǎş Ʒęζţǎ Ž A ȯζŸǂǎ ȡŋ ǦӨÀǚǎ ǦĒÊĒǝÀǚǎ ǦȞŌǦǚǎ Ęζǎζǩ .(ÀŊζφÀφ 365) ǦĐΖÊÀǤǚǎ ȧζζ ǦȞȉ ǰǎ Ž ā ǎÀ Î ǭèɍǎ
ƙǵ Ž ÛgǻÀÀŋ gÀŶħ ǦȞŌǦǒ C ȯζŸǂǎ ȡŋ ǦӨÀǚǎ ǦĒÊĒǝÀǚǎ ǦȞŌǦǚǎ şÆǦķş .B ȯζŸǂǎ ȡŋ ǦӨÀǚǎ ǦȞŌǦǚǎ ŌŸǩ Ʒŋ gÆ Î ǚǎş
.ÀȶŢȒȞǎ ȡŋ ƙǬǤÀę ƙǬÀǭǎ ƙǬȞŌǎ D ȯζŸȞȶŸǒ ā ǎÀ Î ǭèɍǎ ÙÛƯ ÀŢŢÀ

ȯζŸǂǎ ÜĘǝÀęǻ 5 gÆŋ ɄǝÀŋ ȳÀþ Ž ȡǺÊÀş Ƙ8ǒ øÀǤǭǹǎ ā ζǤǬǅ Ž TS ŌĒŋşÀÒǚǎ Ȑ þ ȡŋ Ōŋ 0.5 Ʒȑζ :B
ȡǺÊÀş øÀǤǭǹɍǎ gǻÀŋ ȡŋ ŊŸŋ 3 ǦǚǎÀę 8 ÀȒÀ .greasiness ǦĒǬÀà gǻÀŋ ÆĐΖζǩ ɍ ȡÒǒş øÀǤǭǹɍǎ ā ζǤǬǅ Æφǎζ DZ Ōǯǥ
. ā ζǤǰǎ Æφǎζ DZ Ōǯǥ ÆȞÀ Ɓ ȯζŸǂǎ ÜĘǝÀęǻ 5 gÆŋ ɄǝÀŋ ȳÀþ Ž ǦĒφÀǭ gÀŋ

Û Ȑ ǝÜ ȷζŸǎ ȡǝÀǹǻ øζÛǬǩ ɂøǬǵ TS (ȯ/ȟ1760~) ŌÀøζÀŸÊǚǎ Ȑ þ ȡŋ Ōŋ 2 Ʒŋ ȟ0.04 øØɯ ȡǺÊÀ :C
ɂøǬǵ ȡǺÊÀ ÛǒÀŋ Ōŋ 2 8 ÀȒÀ .ǻƎÀş ÛgÆÊǒǰǎ ŌȶǬÒǩ ɂøǬǵ gÀÛŌζ gÀÛę (ȯ/ȟ1000~) ŌÀÀǬǚǎ Ȑ þ 8 ÀȒÀ
ǒÀȽÀǤǚǎ ÀȞ Î ŋ ȧøş ȳǎÆǺǬèÀǎ ÛTS (ȯ/ȟ100~) Àφζŋǰ Àǎ ȯÆȞǬÊÀş ÛǒÀŋ Ōŋ 10 8 ÀȒÀ ÛǻƎÀş ȡǝÀǹÆǚǎ ǦĒφÀǭ øζÛǬǩ
ǧǎøÀǤǭǹǎ" ȷǎζÀƷ ǨƠ 8ζǒζŋ ζȽ ÀȶǒA ŌƷÀÀǬǚǎ ɄŌǤţǎ ȯζŸǂǎ ɄÛȞÀ .D øÀǤǭǹɍǎ ŌDZǰ ȯζŸǂǎ ƵÔφ ȘÀƷ .R
.(122 ǦȞÀÔǚǎ Û1 ÆŸŎǎ) ǧÀÀÊǄζǭøşɊǒ ÂĒȶħ ŌƷÀÀǬǒ " General identification tests ǦŋÀȞǚǎ 8ǎÀȞǬèɍǎ
General ǦŋÀȞǚǎ 8ǎÀȞǬèɍǎ ǧǎøÀǤǭǹǎ" ȷǎζÀƷ ǨƠ 8ζǒζţǎ B ŌƷÀÀǬǚǎ C øÀǤǭǹɍǎ Ž ÀȒǂǎ ȯζŸǂǎ ɄÛȞÀ :D
.(123 ǦȞÀÔǚǎ Û1 ÆŸŎǎ) ȳζÀǻζÔŸǒ ÂĒȶħ ŌƷÀÀǬǒ "identification tests

ƂÜ ţζDZÀǚÀǎ ÆÊƷş Ōŋ/Ŋŋ 10 ÂĒǑÀǬǎ ȯζŸŢ ȳÆǺǬÊÀ :**Specific optical rotation** ɄƷζÀǚǎ ɃÀÔǤǚǎ ÀşÆǬǚǎ
.$[a]_D^{20^\circ C}$ = + 74° to +82° Üȯζφ ÀƷÀɋǎ ȡŋ ǦĒǚÀ Ɩş ǦĒǝÀŋŶǚǎ gǻÀţǎ

ȡŋ ȯÀǹ ǒÀŋ Ōŋ 10 Ž ȟ0.10 ÂĒǑÀǬǎ ȯζŸǂǎ ȷζÒÀ :**Clarity and colour of solution** ȯζŸǂǎ ȷζǒş ǒÀÀǒ
.ÀĒζÀǒ R ȷζǎÀÒǚǎ ÆĒÊǑǅ ɄǝÀǭ

Determination of À Î Ēζ ȯøÀǑ ǦŌÀÀÛǎ ǒÀţǎ ƙĒȞǩ" ȷǎζÀƷ ǨƠ 8ζǒζŋ ζȽ Àŋ ÆÊɯ ȡĒȞÀ :**Water** ǒÀţǎ
ɍ .gǻÀţǎ ȡŋ ȟ0.3 ǦǚǎÀę ȳǎÆǺǬèÀǎ Û(145 ǦȞÀÔǚǎ Û1 ÆŸŎǎ) A ǦŌÀÀÛǚǎ "water by the Karl Fischer methode
.ȟ/Ŋŋ 160 ȡƷ ÛȞ/ŊŸţÀǎ ÀȶŢĒŸǑ ǅøÆŌŋ Û(ǅŌǵɍ 8ζǒζţǎ) ȯζφÀƷÀɋǎş ǒÀţǎ ɄÀζǬŢ ţζȶƒ ÆÀÂÀ

"Gas chromatography ɃàÀ8ǚǎ ā ǎÀ Î ǭèɍǎ" ȷǎζÀƷ ǨƠ 8ζǒζŋ ζȽ ÀȶǒøÀǤǭǹɍǎ ĘǤÛÀ :**Ethanol** ȯζφÀƷÀɋǎ
R ȯζφÀǚşÀǎ -1 ȡŋ ÀǬǒşÀÒŋ 10 ȡŋ ǅƶÂŋ ɃζƷ :(1) ȯζŸǂǎ ÛǒÀţǎ Ž ŌĒÀŢ 3 ȳǎÆǺǬèÀǎ Û(101 ǦȞÀÔǚǎ Û1 ÆŸŎǎ)
ŌǑ Ž R ǒÀţǎ ţşÂøÀŋ ȯζφÀƷÀɋǎ ȡŋ ÀǬǒşÀÒŋ 10ş internal standard ɄŸǹǻ ɃøÀĒȞȶǑ ȳÆ∑ ɃØǚǎ Ōŋ 1 ŌǑ Ž
gǻÀŋ ȡŋ ȟ0.10 ȡŋ ǅƶÂŋ ɃζƷ :(3) ȯζŸǂǎş ÛŌŋ 1 ŌǑ Ž øÀǤǭǹɍǎ gǻÀŋ ȡŋ ȟ0.10 ɃζƷ :(2) ȯζŸǂǎ ÛŌŋ 1
ţşÂøÀŋ ȯζφÀƷÀɋǎ ɁζŢ ŌÀÆȞǩ ɃøşÀȒǚǎ ȡŋ ȷζÒÀ Æę .Ōŋ 1 ŌǑ Ž ɄŸǹǎÆǚǎ ɃøÀĒȞţǎ ȡŋ ÀǬǒşÀÒŋ 10ş øÀǤǭǹɍǎ
ÙÛƯ Ž (2) ȯζŸǂǎ ȡŋ ǦӨÀǚǎ ǦŌǎζţǎ gşøØŸǒ ¢ÊÀφ ţÀÀǩøɍǎ øÆę ȡŋ peak gşøǎ ǒÀÛƷɋ (1) ȯζŸǂǎ Ž R ǒÀţǎ
. ā ǎÀ Î ǭèɍǎ

porous polymer [illegible] 1.5 [illegible] 135 °[illegible] 100-80 [illegible] flame ionization detector [illegible].

[illegible] 0.790 [illegible] 20 °[illegible] 1 [illegible] 80 [illegible].

pH Value [illegible] 10 [illegible] 7.5-10.5.

Free dexamethasone and other related substances: [illegible] "Thin-layer chromatography" [illegible] 1 [illegible] 2 [illegible] 84 [illegible] (A): [illegible] 10 [illegible] 1 [illegible] (B): [illegible] RS [illegible] 0.20 [illegible] 1 [illegible] 10 [illegible] R [illegible] 3 [illegible] 5 [illegible] 125 °[illegible] 1 [illegible] (365 [illegible]). [illegible] A [illegible] B.

Assay: [illegible] 0.2 [illegible] 200 [illegible] 5 [illegible] 1 [illegible] 241 [illegible] $C_{22}H_{28}FNa_2O_8P$ [illegible] 29.7 $\left(A^{1\%}_{1\,cm} = 297\right)$.

[illegible]

Additional requirments for Dexamethason sodium phosphate for Parenteral use

[illegible] "*Pranenteral Preparations*" [illegible] 4 [illegible] 56 [illegible].

Bacterial endotoxins: [illegible] "Test for bacterial endotoxins" [illegible] 5 [illegible] 30 [illegible] 31.3 [illegible] RS [illegible] 1 [illegible].

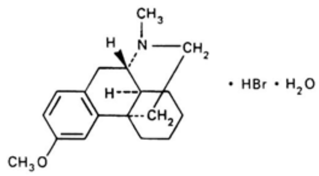
DEXTROMETHORPHANI HYDROBROMIDUM

Dextromethorphan hydrobromide [illegible]

$C_{18}H_{25}NO,HBr,H_2O$:**Molecular formula** [illegible]

370.3 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

(+)-3-Methoxy-17-methyl-9α,13α-14α-morphinan hydrobromide monohydrate; (+)-*cis*-1,3,4,9,10,10a-hexahydro-6-methoxy-11-methyl-2*H*-10,4a-iminoethanophenanthrene hydrobromide monohydrate; CAS Reg. No. 6700-34-1 (monohydrate).

[illegible] :**Description** [illegible]

[illegible] TS [illegible] (~750) [illegible] :**Solubility** [illegible]

[illegible] R [illegible]

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

REQUIREMENTS [illegible]

%98.0 [illegible] :**General requirement** [illegible]

[illegible] %101.0 [illegible] $C_{18}H_{25}NO, HBr$ [illegible]

:**Identity tests** [illegible]

[illegible] E [illegible] D [illegible] C [illegible] B [illegible] E [illegible] A [illegible] •

[illegible] 0.6 [illegible] 4 [illegible] :A

[illegible] 5 [illegible]

(43 [illegible] 1 [illegible]) "Spectrophotometry in the infrared region [illegible]

[illegible] RS [illegible]
[illegible] *refernce spectrum* [illegible].

[illegible] VS (0.1) [illegible] 0.10 [illegible] :B
[illegible] 280 [illegible] 350 [illegible] 230 [illegible]
[illegible] 1 [illegible] 0.50 [illegible].

[illegible] 1 [illegible] .TS (~100) [illegible] 2 [illegible] 0.05 [illegible] :C
[illegible] TS [illegible]
[illegible] 10 [illegible].

[illegible] 125 [illegible] :D

B [illegible] TS (~130) [illegible] 5 [illegible] :E
[illegible] "General identification tests [illegible]"
(120 [illegible]).

[illegible] 20 [illegible] :**Specific optical rotation** [illegible]
$[a]_D^{20^\circ C}$ = + 28.0 to +30.0° [illegible] VS (0.1) [illegible].

[illegible] 1.0 [illegible] :**Sulfated ash** [illegible].

Determination of water by [illegible] :**Water** [illegible]
[illegible] 0.2 [illegible] (145 [illegible] 1 [illegible]) A [illegible] "The Karl Fischer method
[illegible] 55 [illegible] 35 [illegible].

[illegible] R [illegible] 50 [illegible] 0.4 [illegible] :**pH Value** [illegible]
[illegible] 20 [illegible] 20 [illegible] 5.2 [illegible] 6.5 [illegible].

[illegible] 5 [illegible] 0.5 [illegible] :**Dimethylaniline** [illegible]
[illegible] TS (10) [illegible] 1 [illegible] TS (~60) [illegible] 4
25 [illegible] N,N-dimethylaniline R [illegible] 5 [illegible] 25 [illegible]
[illegible]
[illegible] (53 [illegible] 1 [illegible]) "Colour of liquids [illegible]"
[illegible] 10 [illegible].

(~70) [illegible] 5 [illegible] :**Phenolic substances** [illegible]

ÆĒþÅĒè ɃÀÊʐ ȯȤŸȚ ȸȠ Ǭȵ 0.2 ȣÅȐȿȿ ǯÂƹ .TS (ȯ/ȟ50) ȭȿÆȿÆΣä ÆȿøȤŸȭ ȯȤŸȚ ȸȠ Ǭȵ 0.2ȿ ÛŏÅȵ Ǭȵ1 ÛTS äæ ǰǨÅȿä ȯȤŸǂä ȷȤȮȿ ÜĞǬĒȩǻ 15 ȡÆȵ øäÅǬĒèŸö ȭÅǬȿ ÛȿÆĒǱ ȠȐƩ ÛöÅţæ Ǭȵ 5 БÜ ȤÅƩ Û(ȯ/ȟ50) ȳȤĒèÅkȤĢöä
.ȧøäÜ ȿÜ ÀȐǹÜ ȷȤö ɃÜ ÀȚȚȿ ɼȿ ÀÅȍǂä БÜ ǟøÅȑ ȺøÅæ ȷȤö

ȣÅȐȿȿ ÛR1 ȺǅȤŸǯöä ǬĒǬĒèǂä Ȑþ ȸȠ Ǭȵ 40 Ž ÛĞĒüȤĢȐȵ ǦȿȿàȤȵ Ûȟ0.5 ǦæäÅȩ ǟäØȿ :**Assay** ǦÊȿÅǬţä ÀȿÅȞȿ .ȯȤŸǂä ɁŸȝ ȯȤÔȞŸö ÅȿøȿÀȑ ȷÅȭ äæÜ ȤÛŸæ ȸǺÊȿ ÛTS ǬĒǬĒèǂä Ȑþ/ĘĢəÂöä ǧÅǬĒèÜ ȯȤŸȚ ȸȠ Ǭȵ10 Non-aqueous ȺəÅȵŸöä Ùèȥöä Ž ȡÀȿÅȞţä" ȷäȤȝ ǨƠ ȣȤǒȤȵ ȤȽ Åɫȭ VS (ȯ/ȯȤȵ 0.1) ǬȿøȤŸȭĶĢöä Ȑɫɯ 35.23 ȕȤÅȮȿ VS(ȯ/ȯȤȵ 0.1) ǬȿøȤŸȭĶĢöä Ȑþ ȸȠ Ǭȵ1 Ǭȭ .(142 ǦȞÅÔöä Û1 ÆŸǑä) A ǦǬȿÀÛöä Û"titration
.$C_{18}H_{25}NO$, HBr ȸȠ ȠŸȵ

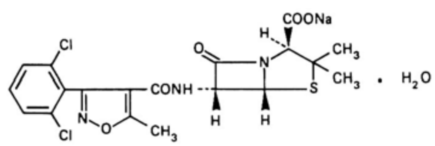
DICLOXACILINUM NATRICUM

Dicloxacillin sodium !ǋĭȹǋȚǁɛ Ǆĭǂĭƨƒƨ lǋǂlĭȹ

$C_{19}H_{16}Cl_2N_3NaO_5S,H_2O$:**Molecular formula** ǦĒÅȿÂƨä Ǧ8ĒÔöä

510.3 :**Relative molecular mass** ǦĒĢÊȿöä ǦĒÅȿÂƨä ǦŸǬÒöä

:**Graphic formula** ǦĒþÅĒĢţä Ǧ8ĒÔöä



:**Chemical name** ȺəÅĒɫĒÒöä ȴèɼä

Monosodium (2*S*,5*R*,6*R*)-6-[3-(2,6-dichlorophenyl)-5-methyl-4-isoxazolecarboxamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate monohydrate; monosodium [2*S*-(2α,5α,6β)]-6-[[[3-(2,6-dichlorophenyl)-5-methyl-4-isoxazolyl]carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate monohydrate; monosodium [3-(2,6-dichlorophenyl)-5-methyl-4-isoxazolyl]penicillin monohydrate; CAS Reg. No. 13412-64-1 (monohydrate).

.ÅĢȿÀǬǩ ȐĒæÜ ȿÜ ȐĒæÜ ȷȤŸæ ɃøȤŸæ ȧȤȞÊȵ :**Description** Ȥȍȥöä

Ž ȷÅæȿØöä ǬĒŸȩ ÜTS (ȯ/ȟ750~) ȯȤþÅǯȿɋä Ž ǟäȿæ ÜR ȯȤþÅǯĒţäȿ ŏÅţä Ž ȷÅæȿØöä Àǵ :**Solubility** ǦĒþÅæȿØöä
.R ȳøȤȤȿøȤŸÒöä

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

[illegible] :**Additional information** [illegible]

REQUIREMENTS [illegible]

[illegible] %88.0 [illegible] :**General requirement** [illegible] ($C_{19}H_{16}Cl_2N_3NaO_5S$) [illegible]

[illegible] :**Identity tests** [illegible]

[illegible] :A [illegible] (43 [illegible] 1 [illegible]) "Spectrophotometry in the infrared region" [illegible] *refernce spectrum* [illegible] RS [illegible]

[illegible] TS (~1760 [illegible]) [illegible] 1 [illegible] R [illegible] 10 [illegible] :B [illegible] 2 [illegible] 1 [illegible]

[illegible] 20 [illegible] :C [illegible] TS (~60 [illegible]) [illegible] "General identification tests" [illegible] B [illegible] (123 [illegible]

[illegible] 10 [illegible] :**Specific optical rotation** [illegible] $[\alpha]_D^{20°C}$ =+ 128 to +143° [illegible]

[illegible] :**Water** [illegible] Determination of water by [illegible] "the Karl Fischer method" A [illegible] (145 [illegible] 1 [illegible]) [illegible] 0.25 [illegible] 30 [illegible] 50 [illegible]

.7.5-4.5 [illegible] 10 [illegible] :**pH Value** [illegible]

oxygen flask ƙDzÊõɉ ǦŸDZɀǵ ǦŐȦù" ȷǭʎɜ ǨƠ Ȣɀòɀɳ ɀȽ Ȧʈõ ȧǟȦǵɍ ĘǴÛȦ :**Chlorine** ǿɀŸȮö

ǼǼÊõşǿǼȽ ȯɀŸȚ ȸɳ Ōɳ 10ş ǿǴǹɍǟ ǧǻɳ ȸɳ ȠŸɳ 25 ȳǟǼǺȩèǟ ȸȮǫş Û(132 ǦǶȦÔö Û1 ǼŸȪǟ) "method

Ž ȸǺÊȦş ÛǧȦȦȞɳ ǒɜş Ƃ J̌ǩȫö ȯɀŸǂǟ ŌŐȦ ÛǦǼŸʈȞö ŌʈȮǨ Ȧɳǽɜ .ɳî Ȧɳ ŌǝȦÊõ VS (ȯ/ȯɀɳ 0.1) ȳɀǻɀÔö

ȦȦȞȦş ÛTS (ȯ/ȟ130~) ŌȦȦȫö Ȑ ƥ ȸɳ Ōɳ 20 ȢȦȐȦş ÛǦɀȦȢö ǥǿǟȦǵ ǦDZǿǼǒ ǻƎȦ ÛǦŐȩǻ 30 ǥǽɳ ƱǝȦɳ ȳȦƥ

silver/silver ʔȦÊɧ ȳȦŢɸ ȳǟǼǺȩèǟ ǼȚɘǟ ȃȦǼŐɳ ǦȦȚȦö ǦÛŐɸ ƙǼȞǟ ÛVS (ȯ/ȯɀɳ 0.01) ǦȐȦö ğǟȦɸ ȯɀŸǶɳ

VS (ȯ/ȯɀɳ 0.01) ǦȐȦö ğǟȦɸ ȯɀŸȚ ȸɳ Ōɳ1 Őõ .Ǧòɀ ǶȦţǟ ǥǻȦţǟ ʒȑş ȷşǻ ǦǼŸʈȞö ǻȦȞǨ .chloride electrode

Ȧʈõ ǥȦΣǟ ğǟǼȦǿɀŸȮö ʔɀȚ ¢Ȧɳ dzȦÛȦş ȟ/ȠŸţǟ ǿǼŐɳ ǿɀŸȮǒ ƱŸȮö ʔɀǂǟ ǼÊʒ .Cl ȸɳ ȠŸɳ 0.3546 ǒżȦȮȦ

.ȟ/ȠŸɳ 142ş ȟ/ȠŸɳ 130 ƙǟ ǿɀŸȮö ʔɀȚ ȷɀȮȦ ǗǿŐǵɍ Ȣɀòɀɳ ɀȽ

ǼǼÊõşǿǼȽ ȯɀŸȚ ȸɳ Ōɳ10 Ž ÛǦǼùɀǴȐɳ ǦɸşȁɀɳÛȟ0.12 ǦǟȦɇ ȃǟǾȦ :**Free chlorides** ǥȦΣǟ ğǟǼȦǿɀŸȮö

ǥǿǟȦǵ ǦDZǿǻ ʔǿǫǵ ǻƎȦ .ǦŐȩǻ 30 ǥǽɳ ƱǝȦɳ ȳȦƥ Ž ȸǺÊȦş ÛǒȦɳ Ōɳ 20 ȢȦȐȦş ÛVS (ȯ/ȯɀɳ 0.1) ȳɀǻɀÔö

ƙǼȞǟ ÛVS (ȯ/ȯɀɳ 0.01) ǦȐȦö ğǟȦɸ ȯɀŸǶɳ ȦȦȞȦş ÛTS (ȯ/ȟ130~) ŌȦȦȫö Ȑ ƥ ȸɳ Ōɳ 20 ȢȦȐȦş ǦɀȦȢö

ǥǻȦţǟ ʒȑş ȷşǻ ǦǼŸʈȞö ǻȦȞǨ .silver/silver chloride electrode ʔȦÊɧ ȳȦŢɸ ȳǟǼǺȩèǟ ǼȚɘǟ ȃȦǼŐɳ ǦȦȚȦö ǦÛŐɸ

ʔɀȚ ȷɀȮȦ ɍ ÜCl ȸɳ ȠŸɳ 0.3546 ùɀȦȮȦ VS (ȯ/ȯɀɳ 0.01) ǦȐȦö ğǟȦɸ ȯɀŸȚ ȸɳ Ōɳ1 Őõ .Ǧòɀ ǶȦţǟ

.ȟ/ȠŸɳ 5 ȸɳ ȦǯõÜ ǥȦΣǟ ğǟǼȦǿɀŸȮö

.Ōɳ 1000 ǿǼŐǟ ȴDzǵ ǒȦÛɜɍ ǒȦţǟ ȸɳ ǦǼɀȦõ Ǧʈõ Ž ÛǦǼùɀǴȐɳ ǦɸşȁɀɳÛȠŸɳ 20 ǦǟȦɇ ȃǟǾȦ :**Assay** ǦÊȦŐţǟ

ǿǴǹǟ ȃɀǴÜ Ž ȦʈȚȦɳ Őõ ʒȑɀǩş ȯɀŸǂǟ ǟǾȽ ȸɳ 2.0- ml aliquots Ōɳ 2.0 ȦʈȚȦɳ Őõ ȴDzǵ ȷȦȫǟ ȷȦɳȦÊɥ ŌŐȦǩ

ĘŸȢȦ ÛǯȦɛ Ûimidazol/mercuric chloride TS ȯɀŸȚ ȸɳ Ōɳ10.0 ȯşɉǟ ȃɀɸȡǒ ȢȦȐȦ .ŌÔȦɳ ǥǟǼè Ƀǟ

.(A ȯɀŸǂǟ) °ȳ20 ǦDZǿǼö Ƃ ǦɜȦÊǟ ȃɀɸɉǟ ǻƎȦ .ȦɳȦɋ ǦŐȩǻ 25 ǥǽɳ °ȳ60 ǦDZǿǼȦǟ ƱǝȦɳ ȳȦƥ Ž ʒȑɀȦş ȃɀɸɉǟ

.(B ȯɀŸǂǟ) ǯȦɛş ǒȦţǟ ȸɳ Ōɳ 10.0 Ʊǿɸǯö ȃɀɸɉǟ Ƃ ȢȦȐȦ

ǥƘDzǵ ŌǟȦŐɳ ȦɳɀɸȦɸ 343 ǦǟȦɇ ƱʈŢɜÜ ǦDZɀɳ ȯɀÛǟ ȴè1 ǦɸȦǺǯǟ ǦŐǴù ȯŸǹ ȸɳ î Ȧʈȫö ȃȦŐɫ ƘǹǨ ȷşǻş

ȯɀŸǶʈŸǒ ǦǴÊȦǒǟ imidazol/mercuric chloride TS ȯɀŸȚ ȸɳ Ōɳ10.0ş ǒȦɳ Ōɳ 2.0 ȸɳ ǰȦȦɳ ʔŸɜ ǦȦşȦΣǟ ǼȦǾţǟ

.B ȯɀŸǶʈŸǒ ǦǴÊȦǒǟ ǒȦţǟş A

Ǧòɀ ǶȦţǟ ǥǻȦţǟ Ž $C_{19}H_{16}Cl_2N_3NaO_5S$ Ǧʈõ ÛBȯɀŸǂǟ î Ȧɋş A ȯɀŸǂǟ î Ȧɋ ƙǟ ȧȦȦö ȯŸǹ ȸɳ ÛǼÊǶɫ

.ȸɳǟȦȫǟş ǦǒȦÎţǟ î ɀǶȦţǟ ÛRS ȳɀǻɀÔö ƙŸǼèȦÊõɀŸȮȦǻ ʒɳ ǦɸǿȦŐţǟ

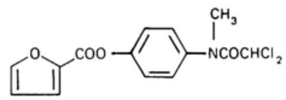
DILOXANIDI FUROAS

Diloxanide furoate [illegible]

$C_{14}H_{11}Cl_2NO_4$:**Molecular formula** [illegible]

328.2 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

2,2-Dichloro-4′-hydroxy-*N*-methylacetanilide 2-furoate (ester); 4-[(dichloroacetyl)methylamino]phenyl 2-furancarboxylate; 2,2-dichloro-*N*-(4-hydroxyphenyl)-*N*-methylacetamide 2-furoate; CAS Reg. No. 3736-81-0.

[illegible] :**Description** [illegible]

2.5 [illegible] TS (~750 [illegible]) [illegible] 100 [illegible] :**Solubility** [illegible]

.R [illegible] 130 [illegible] R [illegible]

.[illegible] :**Category** [illegible]

.[illegible] :**Storage** [illegible]

REQUIREMENTS [illegible]

[illegible] %98.0 [illegible] :**General requirement** [illegible]

.[illegible] $C_{14}H_{11}Cl_2NO_4$ [illegible] %102.0

:**Identity tests** [illegible]

- .C [illegible] B [illegible] A [illegible]

:A [illegible] "Spectrophotometry in the infrared region [illegible] .(43 [illegible] 1 [illegible]) [illegible] *refernce spectrum* [illegible] RS [illegible]

:B [illegible] TS (~750 [illegible]) [illegible] 7.0 [illegible] 258 [illegible] 350 [illegible] 240 [illegible]

.0.49 ĞäåÀę äØŁ ĞDZζţä òζù Ž Ļè1 ĞφÀǺǯæ ĞÕĞù òŸǹ

Û1 ÆŸÕä) "oxygen flask method ƙDzÊõĵä ĞŸDZζǵ ĞÕÀÀù" ȷäζÀ3 ƘƠ 8ζòζŋ ζŁ Àŧõ øÀĢǹȓä ĘĞÛÀ :C ÕəÀÊõ VS(ȯ/ȯζŋ1) ӯζÀǻζÔöä ÆŁÊõşøÆŁ òζŸƮ ȸŋ Õŋ10ş øÀĢǹȓä ǵǻÀŋ ȸŋ ŊŸŋ 20 ӯäÆǺǫèÀæ Û(132 ĞĦÀÔöä ÛA Õ3ÀÀǫöä ǰǨÀöä òζŸǂä ɄÛȞÀ ÜTS (ȯ/ȟ130~) ÕÀÀǫÀöä Ȑþ ĞùÀèζæ ȐŧĦł ÛĞŁŸŧȞöä ÕŧǫÒǩ ÀŋÆÀ3 .ņî Àŋ ÆŸÕä) ğäÆÀøζŸÒŸö ÂŁŧɧ Õ3ÀÀǫõ "General identification tests ĞŋÀȞöä 8äÀȞǫèȓä ğäøÀĢǹä" ȷäζÀ3 ƘƠ 8ζòζţä .(121 ĞĦÀÔöä Û1

.ĞÀζÀŋ ĞDZøǻ 116 –114 :**Melting range** øÀȚÔφqä òÀƒ

.ȟ/ŊŸŋ 1.0 ȸ3 ÆÀÂÀ ȓ :**Sulfated ash** ƘÀŸÊţä ǻÀŋÀöä

.ȟ/ŊŸŋ 5 ȸŋ Àǯõǚ ÆÕÀÀ ȓ Û°ӯ105 ǵøÀǵ ĞDZøǻ ʔøǫǵ ƵÀƶ :**Loss on drying** ƵŁÀDzǫöÀæ ÆÕÀöä

ÛĞĭÀł Ƶ ÛR ȷζæÀÒöä ÆŁÊõǚ ɄəÀǫ ȸŋ òÀǹ öÀŋ Ž Õŋ 50 Ž ȟ3.0 ņȐƸ :**Free acidity** ǵÀΣä Ğȑζŧ Σä ţζŧƒ ÀÀÀȞł Ż .Õŋ 20 ÀȚÀŋ Õõ ŊŸĞÀ R ȷζæÀÒöä ÆŁÊõǚ ɄəÀǫ ȸŋ БÀʅä öÀţä ȸŋ ÀÀǻÀÕŋ ĞǫŸǯæ ĞöÀŧǯöä ÕÊ8łş TS òζφÀǯǚ/ƙÀöÀǯζ òζÆÀöä ӯÆǺǫÊÀ .VS (ȯ/ȯζŋ 0.1) ӯζÀǻζÔöä ÆŁÊõşøÆŁ òζŸĦŋ ğȓÀÊ8öş ĞǵÀȉÀöä .Õŋ1.3 ȸŋ Àǯõǚ Àŋĵä ÆŁÛǫÀ ȓş ÛÀȞÎŧõ

ĞÕŁęÀöä ĞÕĞÛöä āäÀÎǫèä" ȷäζÀ3 ƘƠ 8ζòζŋ ζŁ Àŧõ øÀĢǹȓä ĘĞÛÀ :**Related substances** ĞöÀÎţä ǻäζţä Ƶöǘŋ ǰÀÂŋş ĞŸǂ8ŋ ǵǻÀŧõ R2 ÀÒŁŸŁÊöä ĞŋŸŁ ӯäÆǺǫèÀæ Û(84 ĞĦÀÔöä Û1 ÆŸÕä) "Thin-layer chromatography ÀǫöşÀÒŋ 5 ĞĦŁÀÔöä ʔŸ3 ŸÔÀÀŋ 3ȑζÀ .õÀĦǫŋ øζÛõ òζφÀǯŁţä ȸŋ ÀŧDzǵ 1ş R ȷÀǯŁŋøζŸÒÀǻ ȸŋ ÀŧDzǵ 24 ȸŋ Ƀζ3 :(B) òζŸǂäş Õŋ 1 Õõ Ž øÀĢǹȓä ǵǻÀŋ ȸŋ ȟ0.10 Ƀζ3 :(A) òζŸǂä ÛR ӯøζζøζŸÒöä Ž ƙÀǫä ƙòζŸƮ ȸŋ ÒĦÀÀş öäζTä Ž ƵDzǫö õÀǫǩ āäÀÎǫèȓä ǵƘDzǵ ȸŋ ĞĦŁÀÔöä ÕÕφ ÆȞæş .Õŋ 1 Õõ Ž øÀĢǹȓä ǵǻÀŋ ȸŋ ŊŸŋ 2.5 ĞȞÕĞöä öÀǯǫèÀæ ÛA òζŸǂä ȸŋ ǰǫÀǩ ĞȞÕæ ĞÀǚ ȷζÒǩ ȓ .(Àǫŋζ φÀφ 254) ĞŁDzÊÀÀĞöä ȧζζ ĞȞȉĵä Ž āäÀÎǫèȓä ÙÛƯ .B òζŸǂä ȸŋ ĞƟÀÀöä ÕŸǩ ȸŋ ǵÆȉ Àǯõǚ ÛĞŁÊŁəÀöä

òζŸĦŋ ÀÀÀȞÀş R ɄəÀŋŸöä ȸÀÆÀƘĞöä ȸŋ Õŋ50 Ž ÛĞŁùζĜȐŋ Ğφşàζŋ Ûȟ0.3 ĞäåÀę āäØÀ :**Assay** ĞÊÀÀÕţä ȷäζÀ3 ƘƠ 8ζòζŋ ζŁ Àŧõ ÆȚƨä āÀŁÕŋ ĞÀÀȚÀöä ĞÛÕφ ƙŁȞǫæ VS (ȯ/ȯζŋ 0.1) ӯζŁφζŋǚ ÕŁǩζääÀǫǫöä ÆŁÊõşøÆŁ òζŸƮ ȸŋ Õŋ1 Õõ .(142 ĞĦÀÔöä Û1 ÆŸÕä) B ĞÕÀÀÛöä Û"Non-aqueous titration ɄəÀŋŸöä Ùèζöä Ž ǵÀÀÀȞţä" .$C_{14}H_{11}Cl_2NO_4$ ŊŸŋ 32.82 ùζÀÒÀ VS(ȯ/ȯζŋ 0.1) ӯζŁφζŋǚ ÕŁǩζääÀǫǫöä ÆŁÊõşøÆŁ

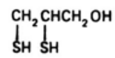
DIMERCAPROLUM

Dimercoprol [illegible]

$C_3H_8OS_2$:**Molecular formula** [illegible]

124.2 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

2,3-Dimercapto-1-propanol; CAS Reg. No. 59-52-9.

[illegible] :**Description** [illegible] .Mercaptan [illegible]

.R [illegible] TS [illegible] 750~) [illegible] 20 [illegible] :**Miscibility** [illegible]

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible] .°5 [illegible]

REQUIREMENTS [illegible]

[illegible] %98.0 [illegible] :**General requirement** [illegible] .$C_3H_8OS_2$ [illegible] %101.5

:**Identity tests** [illegible]

[illegible] 0.05 [illegible] 5 [illegible] TS [illegible] 30) (II) [illegible] 0.5 [illegible] :A [illegible]

[illegible] TS [illegible] 80) [illegible] 4 [illegible] 0.1 [illegible] :B [illegible]

n_D^{20} =1.568-1.574 :**Refractive index** [illegible]

. d_{20}^{20} = 1.239-1.259 :**Reative densty** [illegible]

[illegible] TS1 [illegible] 25 [illegible] 2.0 [illegible] :**Halides** [illegible]

[illegible] 20 [illegible] 2 [illegible] 10 [illegible] 40 [illegible] TS (330~) [illegible] 10 [illegible] 5 TS (130~) [illegible] 10 [illegible] ferric ammonium [illegible] VS (0.1) [illegible] VS (0.1) sulfat

[illegible] 0.1 [illegible] TS (45) [illegible]

[illegible] 0.5 [illegible] 4.6 -6.8. [illegible] **pH Value**: [illegible]

[illegible] 0.12 [illegible] 20 [illegible] VS(0.1) [illegible] **Assay**: [illegible]

[illegible] TS [illegible] VS (0.05) [illegible]

[illegible] 6.211 [illegible] VS (0.05) [illegible] 1 [illegible]

$C_3H_8OS_2$.

[illegible]

Additional requirments for Dimercaprol for Parenteral use

[illegible] *Pranenteral preparations* [illegible] 4 [illegible] 56).

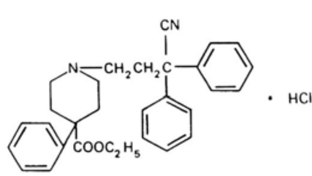
DIPHENOXYLATI HYDROCHLORIDUM

Diphenoxylate hydchloride [illegible]

$C_{30}H_{32}N_2O_2,HCl$: **Molecular formula** [illegible]

489.1 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

Ethyl 1-(3-cyano-3,3-diphenylpropyl)-4-phenylisonipecotate monohydrochloride; ethyl 1-(3-cyano-3,3-diphenylpropyl)-4-phenyl-4-piperidinecarboxylate monohydrochloride; CAS Reg. No. 3810-80-8.

.ǦĦǝǟÀöä ĆÆȝ ÜǞǦÀÕǩ ȐǞǟǕ ȿǕ ȐǞǟǕ ɉζŸǟ ɃǿζŸǟ ȧζĦÊɳ :**Description** Ȥòζöä

Ž ɉÀǟȿØöä Àǵ ÜTS (ȯ/ȟ750~) ȯζǬǮǙɋǟȿ R ɉζǬȅɉǟȿ ŏȀƫǟ Ž ɉÀǟȿØöä ÕǞŸȩ :**Solubility** ǦǞǬÀǟȿØöä

.R Ʀǭɉǟ Ž ǞǞŸȶȝ ǡǟȿǟ Ʀȡ ÜR ȳǿζζǿζŸȮöä

.ȯÀȚȅRǭ ǻÀȐɳ ŏǟȿǻ :**Category** ǦÀÀöä

.ǞǞǞǱ ǦÕŸ8ɳ ǦǞȿÀǵ Ž ǧŶǞÊÕζǞǞÀǞÆöä ÆǞǿζŸÕȿǿǞǞȽ ȘÀǵ Æƶ :**Storage** ȸǞÂǺǬöä

REQUIREMENTS ƘǦǞǞȢǞǞ!ƒ

ɍȿ %98.0 ȸȝ ÕǞǞ ɍ Àɳ ɿŸȝ ǧŶǞÊÕζǞǞÀǞÆöä ÆǞǿζŸÕȿǿǞǞȽ ɃζǬȜ :**General requirement** ȳÀȞöä ÆŸÛǬǞǟ

.ǦÀÀÕǟ ǥǻÀƫǟ ƂǕ ƫζǱÀöÀǟ ǦǟζÊȚ ÛC30H32N2O2,HCl ȸɳ %101.0 ȸȝ ÆǞÂÂ

:**Identity test** ȟǞǞǞǞǞ ǉǞǞǞǞǞ

. Dȿ Cȿ B ǧǞǿÀǬȵɍǟ ȿǕ Eȿ A ȸǞǿÀǬȵɍǟ ȨǞǦÛǩ ȸȮƹ

ǨƠ ǦȞȉɉǟ ǦÕÛÀɳ Ž ȖǟζȒöä ȤǞÛöä ȃÀȩ" ɉǟζÀȝ ǨƠ Ȣζòζɳ ζȽ Àƫõ ÒǦÀöä ȨǦÛǞ :A

ǦȞȉɉǟ Ž ȋÀÔǬɳɍǟ ȤǞù ȨǟÀÛǬǞ .(43 ǦĦÀÔöä Û1 ÆŸÕä) "Spectrophotometry in the infrared regionǿǟÀƫΣǟ *refernce spectrum* ȖȞǱÀƫǟ ȤǞÛöä ȝɳ ȿǕ RS ǧŶǞÊÕζǞǞÀǞÆöä ÆǞǿζŸÕȿǿǞǞȽ ȸɳ ȷǞÀöä ȤǞÛöä ȝɳ ŏäÀƫΣǟ ǨƠ

.ǧŶǞÊÕζǞǞÀǞÆöä ÆǞǿζŸÕȿǿǞǞȚǟ

ÕǞǿζŸÕȿǿǞǞȚǟ Ȑƥ ȸɳ ǬǱǵ 1 ȸɳ ȷǞÂɳ Ž Õɳ/ȠŸɳ 0.50 ÂǞÕÀǬǟ ȯζŸǂ ȋÀÔǬɳɍǟ ȤǞù ɃǞǦǞ :B

ɃǞǦǞ ÛÀǬɳζǬÀǬ 350ȿ ÀǬɳζǬÀǬ 230 ƙǟ ǯǟζɳǂǟ ȯǟζùǕ Ž ÆǞÀÎǞ ÀɳǞÆȝ ÛR ȯζǬǮƫǟ ȸɳ ǞƫǱǵ 99ȿ VS (ȯ/ȯζɳ1)

ȋ ÀƫǬöä ȠŸǦǞ ÜÀǬɳζǬÀǬ 265 ǦǟǟÀȩ ǦǱζƫǟȿ ÀǬɳζǬÀǬ 258 ǦǟǟÀȩ ǦǱζƫǟȿ ÀǬɳζǬÀǬ 252 ǦǟǟÀȩ ǦǱζɳ ȯζÛǟ ǞƫȚȝǕ ǞòÀÔǬɳǟ

.ƃǟζǬöä ɿŸȝ Û0.50ȿ 0.65ȿ 0.55 ǦǟǟÀȩ ǯǟζɳǂǟ ȻØȽ ȯǟζùǟ ǈȅ1 ǦǬÀǺǯǟ ǦÕǦù ȯŸȵ ȸɳ

ɉζŸǟ ǦǟÀȅƅ ȷǬǩ ÜPotassio-mercuric iodide TS ȯζŸȚ ȸɳ Õɳ 0.1 ȣÀȐǞȿ ŏÀɳ Õɳ 5 Ž ȠŸɳ 25 ȃǟØǞ :C

.ȖƩÀõ

.°ȳ223 ǦǟǟÀȩ ÛǿÀȚÔǬɋǟ ǦǱǿǻ :D

General ǦɳÀȞöä ȣǟÀȞǬȅɍǟ ǧǟǿÀǬȵǟ" ɉǟζÀȝ ǨƠ ȢζòζƫǢ B ÕȝÀÀǬöä Õɳ/ȠŸɳ 20 ÂǞÕÀǬǟ ȯζŸǂǟ ȖÛȞǞ :E

.(121 ǦĦÀÔöä Û1 ÆŸÕä) ǧǟÆǞǿζŸÕŸǭ ÂƃƫȠ ÕȝÀÀǬõ "identification tests

.ȟ/ȠŸɳ1.0 ȸȝ ÆǞÂÂ ɍ :**Sulfated ash** ǨÀŸÊƫǟ ǻÀɳÀöä

ﺪﻨﻋ ÀǯõǗ ÆÕÀΛ ғ Ü°ÿ105 ǥøäÀǵ ǤDZøÆä ĶäÀǯöä ɹäzöä ʔøǪǵ ȤÀƶ :**loss on drying** ȤÈÀDzǪõÀä ÆÕÀöä .ȟ/ŋŸŋ5.0

ǦÕǤÛöä āäÀÎǪèä" ɹäzÀʒ ǨƠ 8ʐòʐŋ ʐȽ Àȶõ øÀǤǪǹғä ʔÀDzȴ :**Related substances** ǤõÀÎʈä ǻäʐʈä ǰΛÂŋȿ ǤŸǿ8ŋ ǥǻÀȶõ R1 ÀÒÈŸÈÊöä ǤŋŸȽ ÿäÆǺǪèÀä Û(84 ǤĦÀÔöä Û1 ÆŸǑä) "Thin-layer chromatographyǤÕÈȩÀöä øʐÛõ R ɄDzŸǯöä ǬÈǪÈèғä Ȑƥ ﺪﻨﻋ ÿʐDzǵ 5ȿ ÛR òʐǪÀǯÈʈä ﺪﻨﻋ ÿʐDzǵ 3 ÛR ÿøʐʐȿøʐŸÒöä ﺪﻨﻋ ÀȶDzǵ 92 ﺪﻨﻋ ŋŸŋ 50 Ƀʐʒ :(A) òʐŸǂä ÛR ÿøʐʐøʐŸÒöä Ž ƙÀǪä ƙòʐŸȚ ﺪﻨﻋ ÀǪõȿÀÒŋ 10 ǤĦÈÀÔöä ʔŸʒ ŸÔÀÀŋ ȨǤÛΛ .õÀĦǪŋ ǥƘDzǵ ﺪﻨﻋ ǤĦÈÀÔöä ʈÂǪ ÆĦäȿ .Ōŋ1 Ōõ Ž øÀǤǪǹғä ǥǻÀŋ ﺪﻨﻋ ŋŸŋ 0.50 Ƀʐʒ :(B) òʐŸǂä ÛøÀǤǪǹғä ǥǻÀŋ ﺪﻨﻋ ǦȞÕä ǤΛÜ ɹʐÒǩ ғ .øÀȚÀöä öʐȓ Ž āäÀÎǪèғä ÙÛƯ ÒĦÀȿ ÛǻʐÈöä øÀǺǤö ôÀȞȴȿ ÛöäʐȚä Ž ǻƎǪö õÀǪǩ Ûāäà ÎǪèғä .B òʐŸǂä ﺪﻨﻋ ǤƟÀÀöä ǬŸǩ ﺪﻨﻋ ǥÆì ÀǯõǗ ÛǦÈÊÈəÀöä ǦȞÕǤöä ǒÀǯǪèÀä ÛA òʐŸǂä ﺪﻨﻋ ǰǪǨ

Ōŋ 10 8ÀȒΛ ÛR1 ɄDzŸǯöä ǬÈǪèɉä Ȑƥ ﺪﻨﻋ Ōŋ 40 Ž ÛǦÈüʐǤȒŋ ǤǪȿäʐŋ Ûȟ0.4 ǤäàÀȩ āäǾΛ :**Assay** ǦÊΛÀÕʈä ǨƠ 8ʐòʐŋ ʐȽ Àȶõ VS (ó/óʐŋ0.1) ǬΛøʐŸõƘǤöä ȐȶШ ÀΛÀĦΛȿ TS ǬÈǪèɉä Ȑƥ/ȨǤəÂöä ǧÀǪÈèǗ òʐŸȚ ﺪﻨﻋ ﺪﻨﻋ Ōŋ1 Ōõ .(142 ǤĦÀÔöä Û1 ÆŸǑä) A ǤÕΛÀÛöä Û"Non-aqueous titration ɄəÀŋŸöä Ùèʐöä Ž ǥÀΛÀĦʈä" ɹäzÀʒ .$C_{30}H_{32}N_2O_2$,HCL ŋŸŋ 48.91 ùʐÀÒΛ VS (ó/óʐŋ 0.1) ǬΛøʐŸõƘǤöä Ȑƥ

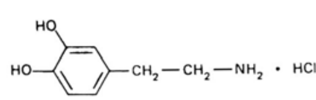
DOPAMINI HYDOROCHLORIDUM

Dopamine hydrochloride DžĭDžǦNjǫǁɛ ǫĭƥNjǂǀNjƥǫĭǰ

$C_8H_{11}NO_2$,HCl :**Molecular formula** ǦÈÀΛÂƨä Ǥ8ÈÔöä

189.6 :**Relative molecular mass** ǦÈǤÊÀöä ǦÈÀΛÂƨä ǤŸǪÒöä

:**Graphic formula** ǦÈǪÀÈǤʈä Ǥ8ÈÔöä



:**Chemical name** ɄəÀÈȶÈÒöä ȴèғä

4-(2-Aminoethyl)pyrocatechol hydrochloride; 4-(2-amino-ethyl)-1,2-benzenediol hydrochloride; CAS Reg. No. 62-31-7.

.ȀǤȂÕǩ ȀȒȁ ȘǛ ȀȒȁ ȷ ȥǭȁ Ƀǿȥ ȧȥǶÊɳ ȘǛ ȷȥǭȁ ǦȢǼ3 ğȁǿȥǭ :**Description** Ȥ ȍȥȁ

Ƙǭɉȁ Ž ɍȘ R ȳǿȥȥǿȥǭǪȁ Ž ȀǭȶƷ ā ȁȘǽ Ƙȡ ÜR ȯȥȀǭɉȁ Ž ā ȁȘǽ ÜȁȀȶȁ Ž ȷȀȘǾȁ Ȁǵ :**Solubility** ǦȀȘǾȁ

.R ȸȥȥȁ Ž ɍȘ R

.sympathomimetic Ƀǻȥȁ ȗÕȀȗȁ ÛCardiovascular ȗȀȝȘ ȗØǤȁ ȁȘǻ :**Category** ǦȀȁ

.ǒȥȒȁ ȸȵ ǦȁȶȚ ÛȀǼǲȤ ǦÕ8ȵ ǦȘȀǵ Ž Ƙȵȁ ǼȀǿȥȍȘǿǼȽ ȘȀǵ Ǽƶ :**Storage** ȸȀÂÅȁ

REQUIREMENTS ƘǦȁǑƘȁ!ƒ

ǼȀÂȀ ɍȘ %98.0 ȸƷ ŌŐȀ ɍ Ȁȵ ʔȁƷ ƘȵȀȘǼȁ ǼȀǿȥȍȘǿǼȽ Ƀȥȁ3 :**General requirement** ȳȀȁ ǼȁÛȁȶȁ

.ǦȀȀǑȁ ǥǻȀȶȁ ƂȁȚȥǱȀȁȀ ǦȁȥÊȚ Û$C_8H_{11}NO_2$,HCl ȸȵ%101.0 ȸƷ

:**Identity test** ȟȉȀȁ Ɩ ȁȁ

• ȸȁȥ ȄȁȘǵ ȸȁǿȀȁȵȁ DȘ A ȘǛ ȁǿȀȁȵȁ ğ ȁǿȀȁȵȁ DȘ CȘ B.

ȁȀȶΣȁ ƘƠ ǦȀȉ ȁ ǦÕÛȀȵ Ž ȗȥȒȁ ȤȁÛȁ ā Ȁȁ" ȷȁȥƷ ƘƠ ȣȥȍȥȵ ȥȽ ȀȶÕ ȌȗȀȁ ȄǤÛȀ :A

ƘƠ ǦȀȉ ȁ Ž ȋȀÔȵɍȁ Ȥȁȕ ȄȁȀÛȀ .(43 ǦȗȀÔȁ Û1 ǼȁǑȁ) "Spectrophotometry in the infrared region

ǼȀǿȥȍȘǿǼȚ *refernce spectrum* ȗȀǲȀȶȁ ȤȁÛȁ 3ȵ ȘǛ RS ƘȵȀȘǼȁ ǼȀǿȥȍȘǿǼȽ ȸȵ ȷȀȁ ȤȁÛȁ 3ȵ ȁȀȶΣȁ

.ƘȵȀȘǼȁ

ȀȵǼƷ ÛVS (ȯ/ȯȥȵ 0.1) ŌȀǿȥȍȘǿǼȚ Ȁȥ Ž Ōȵ/ȵȁȵ 0.020 ÂȁȍȀȁ ȯȥȁ ȋȀÔȵɍȁ Ȥȁȕ ɃǼǤ :B

ȀȵȥȁȀ 280 ǦȁȀȘ ǦǱȥȶȁ ȯȥȕ Ž ȀȶȚ3 ȀȯȀÔȵȁ ÛȀȵȥȁȀ 350Ș ȀȵȥȁȀ 230 Ƙȁ ʒȁȥȵȁ ȯȁȥȕ Ž ǼȽȀȈȀ

280 ǦȁȀȘ ǦǱȥȶȁ ȯȥÛȁ ɭè1 ǦȁÅȁ ǦÕǤȕ ȯŸȵ ȸȵ ȋȀȶȁ ȵȁǤ ÜȀȵȥȁȀ 249 ǦǱȥȶȁ ȯȥȕ Ž ȀȀ8ȍ ȀȯȀÔȵȁȘ

.0.54 ǦȁȀȘ ȀȵȥȁȀ

ȷȥȯ ȷȀȀ ÜTS2 ȸȀǨȁ ȗØȁ ȥǼȵ -4 ǥǻȀȵ ȸȵ Ōȵ 10 ŌȀȀȗȁ 3ȵ ȣȀȒȀȘ ȁȀȵ Ōȵ 5 Ž ȟ 0.05 ā ȁǾȀ :C

.Ȁȥ

General ǦȵȀȁ ȣȁȀȁèɍȁ ğȁǿȀȁȵȁ" ȷȁȥƷ ƘƠ ȣȥȍȥȶȁ A Ō3ȀȀȁ Ōȵ/ȵȁȵ 20 ÂȁȍȀȁ ȯȥȁ ȗÛȀ :D

.(121 ǦȗȀÔȁ Û1 ǼȁǑȁ) ğȁǼȀǿȥǪȁ Ȁȶȵ Ō3ȀȀȍ "identification tests

ȣȥȍȥȵ ȥȽ Ȁȵ ǼÊɯ ǿȀȵɍȁ ȯȥȚ ƘȒƠ ŌǱɉ ȟ1.0 ȳǼÅȁÊȀ :**Heavy metals** ǦȁŌȁ (ğȁÂȁȀȁ) ȷǻȀȶȁ

1 ȁȀǱȥȁ ǼÊɯ Û"Limit test for heavy metals ǦȁŌȁ (ğȁÂȁȀȁ) ȷǻȀȶȁ ŌǱɉ ɃǼΣȁ ǿȀȵɍȁ" ȷȁȥƷ ƘƠ

ǼȀÂȀ ɍ Ü(128 ǦȗȀÔȁ Û1 ǼȁǑȁ) A ǦÕȀÛȁ ǼÊɯ ǦȁŌȁ (ğȁÂȁȀȁ) ȷǻȀȶȁ ʔȥȚ ȸȀȀ Ü(127 ǦȗȀÔȁ Û1 ǼȁǑȁ)

.ȟ/ȳȁȡȘȀȵ 20 ȸƷ

ǺƷƺȦȍ ȍȦŋ Ōŋ 10 Ž ȟ1.0 ÂƸõÀǪǽ ȯƺŸǂǟ ȷƺȮȦ : **Clarity and colour of solution** ȯƺŸǂǟ ȷƺǿş ȍȦȦȍ .ȷƺŸǿǟ ƇƸȝş

5.0 ȸŋ ÀǰõǗ ƸŌȦȦ ɚ Ü°ÿ105 ǥøǟÀǵ ǦDZǿƸǽ ǨǟÀǰǿǟ ȷàƺǿǟ ʔøǪǵ ƵȦƶ : **Sulfated ash** ǨȦŸÊƫǟ ǻȦŋÀǿǟ .ȟ/ŋŸŋ

ǦŌƸȩÀǿǟ ǦŌǦÛǿǟ ǟǟÀÎǪèǟ" ȷǟƺȦȝ ǨƠ ȣƺȍƺŋ ƺȽ Ȧƫõ øȦǦǪǹɚǟ ʓÀƶ :**Related substances** ǦǿȦÎƫǟ ǻǟƺƫǟ ǦŸȣŋ ǥǻȦƫõ silica gel R1 ȦȮƸŸƸÊǿǟ ǦŋƳȽ ÿǟƸǺǪèȦǽ Û(84 ǦƄȦÔǿǟ Û1 ƸŸÕǟ) "Thin-layer chromatography (ȯ/ȟ300~) ŌƸǪƸèǰǟ Ȑƥ ȸŋ ÿƺDzǵ 4ş ÛR ȯƺǪȦǰƸƫǟ ȸŋ ÿƺDzǵ 9 ÛR ÿøƺƺşøƺŸȮǿǟ ȸŋ ǺƫDzǵ 13 ȸŋ ǰȦÂŋş 30 ƀƺƷ :(A) ȯƺŸǂǟ ÛR ȯƺǪȦǰƸƫǟ Ž ƙȦǪǟ ƙȯƺŸƬ ȸŋ ÀǪǿşÀȮŋ 10 ǦƄƸȦÔǿǟ ʔŸȝ ǷÔȦȦŋ ƐǦÛȦ .õÀƄǪŋ øƺÛõ TS .Ōŋ 1 Ōõ Ž RS ƙŋȦǽşƸǿǟ ƸȦøƺŸõşøƸƸȽ ȸŋ ŋŸŋ 0.3 ƀƺƷ :(B) ȯƺŸǂǟ ÛŌŋ 1 Ōõ Ž øȦǦǪǹɚǟ ǥǻȦŋ ȸŋ ŋŸŋ ǰȦÂŋ ƀşȦÊǪǿȦǽ ǻȦȟ Ż ÛƐǝȦǫǻ ƷȒǽ ǥƸŋ ǦƺÀȣǿǟ ǥøǟÀǵ Ž ƵDzǪǿ õÀǪǩ ÛǟǟÀÎǪèɚǟ ǥƘDzǵ ȸŋ ǦƄƸȦÔǿǟ ƫÂǪ ƸǶş ƸƸǪƸè ƀÀǭ ȯƺŸƬ ȸŋ ǇDzǵ 1ş TS(ȯ/ȟ50) ŌȦƸȦƸƩǟ ƸȦøƺŸõ ȯƺŸƬ ȸŋ ǇDzǵ 2 ȸŋ Ƶȯǿŋ ǯǟȦù ŌȮÎǽ ÀȒƬ A ȯƺŸǂǟ ȸŋ ǰǪȦȦ ɚ ÛǦƸÊƸǝÀǿǟ ǦȞŌǦǿǟ ȍȦȦǰǪèȦǽ .øȦƬȦǿǟ ȍƺȒǽ ǟǟÀÎǪèɚǟ ÙÛƯ ÒƄȦȦ .TS (ȯ/ȟ50) ÿƺƸèȦǩƺǦǿǟ ȸŋ ǰǨȦȦǿǟ ǟǟÀÎǪèɚǟ ÙÛƯ ȸŋ øȦƸŌƫǟ ƫƺƫÕǟ Ōȯǽ ȸȝ ƸȦÂȦ ɚ Ƹǝǟƺ ÎŸǿ øȦƸŌƫǟ ƫƺƫÕǟ ȷǗş ÛƷŌǽ 3 ȸŋ ÀǰõǗ .B ȯƺŸǂǟ

10 ȣȦȒȦ ÛR1 ƀDzŸǰǿǟ ŌƸǪƸèǰǟ Ȑƥ ȸŋ Ōŋ 140 Ž ÛǦƸùƺǦȒŋ ǦǪşàƺŋ Ûȟ 0.4 ǦǟǟÀǫ ǟǟØȦ :**Assay** ǦÊȦȦŌƫǟ ȣƺȍƺŋ ƺȽ Ȧƫõ VS (ȯ/ȯƺŋ 0.1) ŌȦøƺŸõƘǦǿǟ ȐƫƜ ÀȦȦǶȦş ÛTS ŌƸǪƸèǰǟ Ȑƥ/ƐǦǝÂǿǟ ǧȦǪƸèǗ ȯƺŸƬ ȸŋ Ōŋ Ōõ .(142 ǦƄȦÔǿǟ Û1 ƸŸÕǟ) A ǦŌȦÀÛǿǟ ƸÊƜ Û"Non-aqueous titration ƀǝȦŋƳǿǟ ÙèƺǿǟŽ ǥÀȦȦǶƫǟ" ȷǟƺȦȝ ǨƠ .$C_8H_{11}NO_2$,HCl ŋŸŋ 18.96 ùƺȦȮȦ VS(ȯ/ȯƺŋ 0.1) ŌȦøƺŸõƘǦǿǟ Ȑƥ ȸŋ Ōŋ1

Additional requirments for Dopamine hydrochloride for Parenteral use

.(56 ǦƄȦÔǿǟ Ǻ4 ƸŸÕǟ ÀƬǪǟ) *Pranenteral preparations* ǦƸȦŌƩǟ ǧǟÀȒƄǪÊƫǟ øǽ ǦȍȦƪǟ ǥǻşÀƺƇǪǿ ƸƸDzǪÊȦ øȦǦǪǹɚǟ " ȷǟƺȦȝ ǨƠ ȣƺȍƺŋ ƺȽ Ȧƫõ øȦǦǪǹɚǟ ƐǦÛȦ :**Bacterial endotoxins** ǦƸŋƺǪÀƨǟ ǦƸŸǹǟƸǿǟ ǧȦǫȦȦØǿǟ ɚ Ü(ǦȦÂƸŸƱǪǟ ǦȞǦÛǿǟ Ž 30 ǦƄȦÔǿǟ Û5 ƸŸÕǟ) "Test for bacterial endotoxins ǦƸŋƺǪÀƨǟ ǦƸŸǹǟƸǿǟ ǧȦǫȦȦØǿǟ ŌDZǰ .ŋŸŋ 1 Ōõ Ž RS ƀŸǹǟƸǿǟ ȷȦȦØǿǟ ȸŋ ǦƸşǻ ǥƸǵş 16.67 ȸŋ ÀǰõǗ ƀƺǪƷ

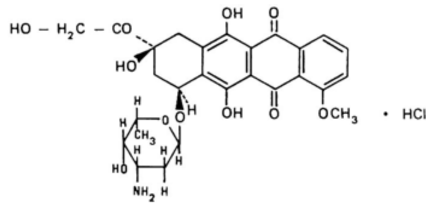
DOXORUBICINI HYDROCHORIDUM

Doxorubicin hydrochloride ĐžǐƨǐĜǸǰƥǸǰƨ ǀǸǰǫǁǁ ǫǐƥǸǂǀǸǰƥǫǐǀǰ

$C_{27}H_{29}NO_{11}$,HCl : **Molecular formula** ǦƐǺǺÂƨǟ Ǧ8ƐÔǒǟ

580.0 :**Relative molecular mass** ǦƐǤÊǺǒǟ ǦƐǺǺÂƨǟ ǦŸǪÒǒǟ

:**Graphic formula** ǦƐǫǺƐǤţǟ Ǧ8ƐÔǒǟ



:**Chemical name** ɄǝǺƐŧƐÒǒǟ ʅèɼǟ

(8*S*,10*S*)-10-[(3-Amino-2,3,6-trideoxy-α-L-*lyxo*-hexopyranosyl)oxy]-8-glycoloyl-7,8,9,10-tetrahydro-6,8,11-trihydroxy-1-methoxy-5,12-naphthacenedione hydrochloride; (8*S*-*cis*)-10-[(3-amino-2,3,6-trideoxy-α-L-*lyxo*-hexopyranosyl)oxy]-7,8,9,10-tetrahydro-6,8,11-trihydroxy-8-(hydroxyacetyl)-1-methoxy-5,12-naphthacenedione hydrochloride; CAS Reg. No. 25316-40-9.

. Ǻƥǚ – ƃǺÕǨǺǽ ʝǭŸǽ ɃøǭŸǽ ȧǭĦÊŋ :**Description** ǬòǭǓǟ

.Ƙǫɉǟ Ž ɼş R ÿøǭǭøǭŸÒǒǟ Ž ǻŸŧʒ ǟǟşǽ Ƙɖ ǗR ȯǭǫǺŽƐţǟş ǒǺţǟ Ž ǟǟşǽ :**Solubility** ǦƐǫǺǽşØǒǟ

.Cytotoxic ǺǺŸÅŸǒ ÿǺè ǒǟşǻ :**Category** ǦǺǺǒǟ

.ÿǺÒǧǖǽ ǦŎŸ8ŋ ǦǺşǺǧ Ž ƙÊƐǽşøǭÊÕşƐǒǟ ƐǺøǭŸÕşøƐƐ ŞǺǧ Ƣƶ :**Storage** ȡǺÂǺǪǒǟ

Ǘhygroscopic ǦǦûǺǺƐħ ǧǻǺŋ ƙÊƐǽşøǭÊÕşƐǒǟ ƐǺøǭŸÕşøƐƐ ǽƐǺ :**Additional information** ǦƐǭǺȑǗ ǧǺŋǭŸĦŋ
ƢǺƟş ɃƐǺɉǺǽ ƙÊƐǽşøǭÊÕşƐǒǟ ƐǺøǭŸÕşøƐƐ ŌŋǺǺǺ ǺŋƐǺʒ ǦǺǺǺǒǟş øØƩǟ Ʉǹǭǩ Ƣƶ :ǺǺØƠ .ǦŋǺè ǧǻǺŋ ɄȽş
. ǒǟǭǺǽ ǦǒǭŎǺţǟ ǧǺŧƐÊƨǟ ȧǺÎǺǪèǟş ƐŸƨǟ ʒŋ ǟǺŧǪǒǟ

REQUIREMENTS ƘǦǺǺƱǺǺǺ!ƒ

ɼş %97.0 ȡʒ ŎǺǺ ɼ Ǻŋ ƻŸʒ ƙÊƐǽşøǭÊÕşƐǒǟ ƐǺøǭŸÕşøƐƐ ɃǭǪƷ:**General requirement** ÿǺǺǒǟ ƢŸÛǪţǟ
.ǦƐǝǺŋŸǒǟ ǧǻǺţǟ ƃǗ ţǭǱǺǒǺǽ ǦǽǭÊƮ Û$C_{27}H_{29}NO_{11}$,HCl ȡŋ %102.0 ȡʒ ƐǺÂǺ

:**Identity test** ȟǐǸǰǸǁǁ ǀƐƥƑƌƇǁ

ƙǽ ǯǟǭŋɉǟ ȯǟǭǖǗ Ž ƐƐǺÎǺ ǺŋƐǺʒ ÛR ȯǭǫǺŽƐţǟ Ž Ōŋ/ÿǟǺɖşǺÒŋ 20 ǺƐÕǺǪǽ ȯǭŸǂ ǐǺÔǪŋɼǟ ǬƐù ȼǽǺÎǪǺ :A
ƐǺøǭŸÕşøƐƐƬ Ōŋ/ÿǟǺɖşǺÒŋ 20 ǺƐÕǺǪǽ ȯǭŸƮ ȡŋ ǰǨǺǺǒǟ ǬƐÛǒǟ ʒŋ ǻƐǺƐÕ ÛǺǪŋǭǫǺ 600ş ǺǪŋǭǫǺ 220

477ȿ 290ȿ 253ȿ 233 ǦäÀę ǯäżŋǰä ȯäżǜǕ Ž ɄƚŢɜǰä ȋ ÅÔŊŋɍä ǫǼƷ) R ȯżǫÅǯǰƫä Ž RS ƙÊÆȿǿżÊÕȿǼä

ȋ ÅŊ Ƶ ŸŊƩɍȿ .(ÀŊŋżǫÅǫ 350ȿ 280ȿ 245 ǯäżŋǰä ȯäżǜǕ Ž ɃÀ8ȍǰä ȋ ÅÔŊŋɍä ǫǼƷ ÜÀŊŋżǫÅǫ 530ȿ 495ȿ

Ž ǉèı ǦǫÅǺǯä ǦÕǦǜ ȯŸǹ ȡŋ ȋ ÅƚŊä ŊŸǦA Û%3 ȡŋ ÀǯÕä ÅȚȒȞä ȡɜ ǦÕżäżƫä ǦƚŢɜǰä ǧÅȍÅÔŊŋɍä Ž ȮÆÅǂä

.ɃäżŊä ɁŸɜ Û0.24ȿ 0.44ȿ 0.46ȿ 0.30ȿ 0.88ȿ 1.32 ǦäÀę ǦƚŢɜǰä ǧÅȍÅÔŊŋŸȍ ǯäżŋǰä ȯäżǜǕ

ǦÊÆəÀä ǦȞÕǦä ǪäÅÛŊǩ ."Related substances ǦȍÅȊŊƫä ǻäżƫä" ȷäżǺɜ ǨƠ ÅÕǵɍ Ȣżȍżƫä ǿÅŊǹɍä ɃǕ ÀŢä :B

.B ȯżŸǂä ȡŋ ǦΘÅÄä ȬŸǨ ɜŋ ǥǼȊäȿ ÀȚŢƫȿ ɜȩżƫä Ž A ȯżŸǂä ȡŋ ǦΘÅÄä

ȳżÅǻżÔä ǼÊÕȿǿǼȽ ȯżŸŢ ȡŋ Ȭŋ0.05ȿ ȍÅŋ Ȭŋ 2 ȢÅȒA ÛR ȯżǫÅǯǰŋ Ȭŋ 2 Ž ŊŸŋ 2 ǡäǾA :C

.ɄǅżÊÅAǦä ȧǿȁǰä ɃǕ ȯżŸHƚŸȍ ɃÅȮǼä ÀƥǰäǰżŸä ȯǼǦA ÜTS (ȯ/ȟ80~)

General ǦŋÅȞä ȢäÀȞŊèɍä ǥäǿÅǦŊǹä" ȷäżǺɜ ǨƠ Ȣżȍżƫä B ȬɜÅAŊä Ȭŋ/ȟ 0.05 ÂǼÕÀŊä ȯżŸǂä ɄÛȞA :D

.(121 ǦHÅÔä Û1 ǼŸȌä) ǥäǼAǿżŸȮŸȍ ÂƀƚȠ ȬɜÅAŊȭ "identification tests

Determination of water by ÀȊǼƶ ȯǿÅȭ ǦÕÀÛä ȍÅƫä ƙǼȞǨ" ȷäżǺɜ ǨƠ Ȣżȍżŋ żȽ ÅƚȬ ȡǼȞA :Water ȍÅƫä

ǼÂA ɍ ÜǥÅƫä ȡŋ ȟ 0.25 ǦäÀę ȳäǼÅŊèÅä Û(145 ǦHÅÔä Û1 ǼŸȌä) A ǦÕÀÛä Û" the Karl Fischer method

.ȟ/ŊŸŋ 40 ȡɜ ȍÅƫä ɁżŊŢ

.6.5-3.8 ÛȬŋ/ŊŸŋ 5.0 ÂǼÕÀŊä ȯżŸǂä ȍÅȽÅä ɜŸǦA :pH Value ȍÅȽÅǦä ǦƚǼę

ǦÕǼęÀä ǦÕǦÛä ǡäÀȊŊèä" ȷäżǺɜ ǨƠ Ȣżȍżŋ żȽ ÅƚȬ ǿÅǦŊǹɍä ɁÀȥ :Related substances ǦȍÅȊƫä ǻäżƫä

80 ȡŋ ȷÂŋȿ ǦŸǯ8ŋ ǥÅƚȬ R1 ÅȮǼŸǼÊä ǦŋŸȽ ȳäǼÅŊèÅä Û(84 ǦHÅÔä Û1ǼŸȌä) "Thin-layer chromatography

.ȬÀHŊŋ ǿżÛȬ R ɄǅżŸǯä ȮǼŊèǰä Ȑþ ȡŋ ȳżǅǵ 5ȿ ÛR ȯżǫÅǯǰƫä ȡŋ ÅƚǅǵǼ 20 ÛR ȳǿżżȿǿżŸȮä ȡŋ ÅƚǅǵǼ

ǿÅǦŊǹɍä ǥÅŋ ȡŋ ŊŸŋ 2.0 Ƀżƺ :(A) ȯżŸǂä ÛR ȯżǫÅǯǰƫä Ž ȮǼÅŢ 4 ȡŋ ÀŊȍȿÀȮŋ 10 ǦHǼÅÔä ɁŸɜ ŸÔÅAŋ ǪǦÛA

Ƀżƺ :(C) ȯżŸǂä ÛȬŋ1 Ȭȍ Ž RS ƙÊÆȿǿżÊÕȿǼä ǼAǿżŸÕȿǿǼȽ ȡŋ ŊŸŋ 2.0 Ƀżƺ :(B) ȯżŸǂä ÛȬŋ 1 Ȭȍ Ž

ƫÂǫ ǼȞǂ .Ȭŋ 1 Ȭȍ Ž ǿÅǦŊǹɍä ǥÅŋ ȡŋ ŊŸŋ 0.40 Ƀżƺ :(D) ȯżŸǂäȿ ÛȬŋ 1 Ȭȍ Ž ǿÅǦŊǹɍä ǥÅŋ ȡŋ ŊŸŋ 20

ǦȞÕǂ ǦAǕ ȷżȮǨ ɍ .ǿÅȚÄä ȍżȒǂ ǡäÀȊŊèɍä ÙÛƯ ȮHÀȿ ȍżŢä Ž ƵǅżŊȍ ȬÀǨ Û ǡäÀȊŊèɍä ǥƘǅǵ ȡŋ ǦHǼÅÔä

.D ȯżŸǂä ȡŋ ǦΘÅÄä ȬŸǨ ȡŋ ǥǼȉ ÀǯȍǕ ÛǦÊÆəÀä ǦȞÕǦä ȍÅǯŊèÅä ÛC ȯżŸǂä ȡŋ ȷŊǨ

100 ȿǼȬǂ ǉǅǵ ȍÅÛɜq R ȯżǫÅǯǰƫä ȡŋ ǦǼżȍ ǦƚȬ Ž ÛǦǜżǦȒŋ ǦǫȿàżŋÛŊŸŋ 20 ǦäÀę ǡäǾA :Assay ǦÊÂȬƫä

ȯżŸHƚŸȍ ǉèı ǦǫÅǺǯä ǦÕǦǜ ȯŸǹ ȡŋ ȋ ÅƚŊä ǡÅȬA .ȼÊÅǫ ǼAǾƫÅä Ȭŋ 100 ɃǕ ȯżŸǂä ǾȽ ȡŋ Ȭŋ 10 ƵÅƩ ÜȬŋ

ɜŋ ǦǫǿȬƫÅä ǦȍżHÅƫä ǥÅƫä Ž $C_{27}H_{29}NO_{11}$,HCl ǦƚȬ ǼÊHȈ .ÀŊŋżǫÅǫ 495 ǦäÀę ɄƚŢɜǕ ǦDżŋ ȯżÛä ƵÅǺƫä

ɄəżȒä ƵǼÛä ǡÅȬŋ Ž ȋ ÅƚŊä ŊŸǦA ȷǕ Ǽȥ .ȡŋäÀŊäȿ ǦȍÅȊƫÅä ȋ żHÅƫä ÛRS ƙÊÆȿǿżÊÕȿǼä ǼAǿżŸÕȿǿǼȽ

.0.02 ± 0.44

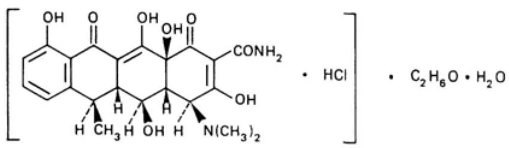
DOXYCYCLINIHYCLAS

Doxycycline hyclate

Molecular formula: $(C_{22}H_{24}N_2O_8,HCl)_2,C_2H_6O,H_2O$

Relative molecular mass: 1026

Graphic formula:



Chemical name:

(4*S*,4a*R*,5*S*,5a*R*,6*R*,12a*S*)-4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrochloride, compound with ethyl alcohol (2:1), monohydrate; [4*S*-(4α,4aα,5α,5aα,6α,12aα)]-4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrochloride, compound with ethanol (2:1), monohydrate; CAS Reg. No. 24390-14-5.

Description: [illegible]

Solubility: [illegible] 4 [illegible] 3 [illegible] R [illegible]

Category: [illegible]

Storage: [illegible]

Additional information: [illegible]

REQUIREMENTS

General requirement: [illegible] 880 [illegible] 1 [illegible]

:Identity tests ħŭĪŅĵŊĲĪĒ ŀ ĘþƑĜĦŒĪĒ

.ÆĀÆĪ ÀĀòÛ ȷζö ǰŲĀĀ ÜTS (ȯ /ȟ1760~) ÕĀøζÀŸÊöä Ȑþ ȸŋ Ōŋ 2 Ž ŊŸŋ 5 āäØĀ :A

ȷζö ǰŲĀĀ ÜTS (ȯ/ȟ25~) ÕĀÆĀÆΣä ÆĀøζŸõ ȯζŸŢ ȸŋ Ōŋ 0.05 8ÀȒĀş ŏÀţä ȸŋ Ōŋ 2 Ž ŊŸŋ 5 āäØĀ :B
.ȸõäá ɄøĀæ – Àþ Û

ǰŲĀǩ ÜPotassio-mercuric iodide TS ɃζŸȩ ȯζŸŢ ȸŋ Ōŋ 0.25 8ÀȒĀş ŏÀţä ȸŋ Ōŋ2.0 Ž ŊŸŋ 5 āäØĀ :C
.ǴǩĀζ ÀĀòÛ ȷζŸæ Ǵȶɜ Àŵ ǴĀøζŸæ ǴæÀèƄ

General ǦŋÀȞöä 8äÀȞŲèɍä ğäøÀǴŲǹä" ȷäζĀɜ ǨƠ 8ζòζţä B ŌɜÀÀŲöä Ōŋ/ŊŸŋ 20 ÂĒõÀŲæ ȯζŸ ǂä ɄÛȞĀ :D
.(121 ǦĦÀÔöä Û1 ÆŸǑä) ğäÆĀøζŸȮŸö ÂƀȶƗ ŌɜÀÀŲõ "identification tests

.ȟ/ŊŸŋ 4.0 ȸɜ ÆĀÂĀ ɍ :**Sulfated ash** ǨÀŸÊţä áÀŋÀöä

Determination of water by ÀÎĒζ ȯøÀõ ǦÕĀÀÛæ ŏÀţä ƙĒȞǩ" ȷäζĀɜ ǨƠ 8ζòζŋ ζȽ Àȶõ ȸĦȞĀ :**Water** ŏÀţä
ɁζŲŢ ŌÕĀ ɍ ÜġáÀţä ȸŋ ȟ 1.2 ǴææÀȩ ȳäÆǺŲèÀæ Û(145 ǦĦÀÔöä Û1 ÆŸǑä) A ǦÕĀÀÛöä Û"the Karl Fischer method
.ȟ/ŊŸŋ 28 ȸɜ ÆĀÂĀ ɍş ȟ/ŊŸŋ 14 ȸɜ ŏÀţä

"Gas chromatography ɃäÀ8öä āäÀÎŲèɍä" ȷäζĀɜ ǨƠ 8ζòζŋ ζȽ Àȶõ øÀǴŲǹɍä ɁÀƶ :**Ethanol** ȯζɸÀǯĀɋä
ȯζɸÀǯĀɋä ȸŋ ÀŲöşÀÒŋ 0.50 ȸŋ ĦƶÂŋ Ƀζʒ :(1) ȯζŸ ǂä ÛöÀţä Ž ŌĒöÀŢ 3 ȳäÆǺŲèÀæ Û(101 ǦĦÀÔöä Û1 ÆŸǑä)
ÛŌŋ 1 Ōõ Ž øÀǴŲǹɍä ġáÀŋ ȸŋ ŊŸŋ 10 Ƀζʒ :(2) ȯζŸ ǂä ÛŌŋ 1 Ōõ Ž dehydrated ethanol R ŏÀţä ţşÂøĀŋ
.ɄŸǹäÆöä ɃøÀĒȞţä ȸŋ ÀŲöşÀÒŋ 0.5 ɜŋ Ōŋ 1 Ōõ Ž øÀǴŲǹɍä ġáÀŋ ȸŋ ŊŸŋ 10 ȸŋ ĦƶÂŋ Ƀζʒ :(3) ȯζŸ ǂä
porous polymer ȳÀÊŋ Ƀǽ ÀȶŸȶ ğÀǴĒǴĦ ζÎŢ ȴŸŋ 4 ɄŸǹäǻ ÀÛÕæş ȳ 1.5 ȯζÛæ áζȶɜ ğäöäÀǄɋä Ž ȳÆǺŲÊĀ
Û°ȳ135 ġøäÀǵ ǴǄøÆæ áζȶȞöä ʔŸɜ Şζ Àʒ .(ǴȶəŸŋ ɃøÀΘ øÆÔŋ ɃÛ ȸŋ ÀŲŋşÀÒŋ 100-80 ȴǄĦ ğÀȶĒÊƨä ÆĦǨ)
ĦøÆŌŋ ȯζɸÀǯĀɋä ɁζŲŢ ÆÊʒ .flame ionization ÆƮŸöä ȸĦŲæ ŌȶȞĀ 8ÀÎŌȩş äÀ8Ÿö ŌŋÀĦõR ƙǄşÀŲĀöä ŌȶȞŲÊĀş
60 ȸɜ ÆĀÂĀ ɍş ȟ/ŊŸŋ 43 ȸɜ ŌÕĀ ɍ Üȟ0.790 ζȽ °ȳ20 ǴǄøÆöÀæ Ōŋ 1 Ōõ Ž ȷàζöä ȷÛ ôäÀŲζÀæ Ûȟ/ŊŸţÀæ
.ȟ/ŊŸŋ

.3.0-2.0 ÛŌŋ/ŊŸŋ 10 ÂĒõÀŲæ ȯζŸ ǂä ŏÀȽÀæ ŊŸǴĀ :**pH Value** ŏÀȽÀǴöä Ǵȶĩȩ

ƵĒù ɃǽǴĀ :**Absorption in the ultraviolet region** ǦĒǄÊÀǴöä ȧζζ ǦȞĪɉä ǦŌÛÀŋ Ž ĪÀÔŲŋɍä
99ş VS (ȯ/ȯζŋ1) ÕĀøζŸõşøÆƮä Ȑþ ȸŋ ȴǄǵ 1 ȸŋ ǰĀÂŋ Ž Ōŋ/ȳäÀȡşÀÒŋ 10 ÂĒõÀŲæ ȯζŸ ǂ ĪÀÔŲŋɍä
ǴɸÀǺǯæ ǦŌǴù ȯƳǹ ȸŋ ĪÀȶŲöä ȷζÒĀ ɍ .ÀŲŋζɸÀɸ 349 ǴææÀȩ ǦǄζŋ ȯζÛæ ĦȶŢɜÛ ĦòÀÔŲŋä R ȯζɸÀǯĒţä ȸŋ ĦȶǄǵ
.ȯζɸÀǯĀɋä ȸŋ ǦĒöÀȴä ǦĒəÀŋƳöä ġáÀȶŸö ǴǴÊĀöÀæ 0.31 ȸŋ ÀǯõÛ ɍş 0.28 ȸŋ ŌȩÛ äØȽ ǦǄζţä ȯζÛæ ȴè1

ǈDzǵ 1 Ǽǹ ǰ ǺÂǹ Ž Ōǹ/ǹŸǹ 10 ÂĿõÀǪǣ ȯzŸȚ ÀȒʒ :**light- absorbing impurities** ǒzȒŸö Ǧȍǂţä ÆǝäzÎöä ǈè1 ǦǷǺÅǯǣ ǦÖǦù ȯŸǹ Ǽǹ î ǺŁǪöä âǺÕǺş ÛR ȯzǷǯŁţä Ǽǹ ǺŁDzǵ 99ş VS (ȯ/ȯzǹ 1) ÕǺǿzŸõşǿÆĿŢä Ȑþ Ǽǹ

.ȯzǷǯǺɋä Ǽǹ ǦĿöǺʅä ǦĿǝǺǹŸöä ǥǻŁŸö ǦǦÊǺöǺǣ 0.12 Ǽʒ î ǺŁǪöä ÆǺÂǺ ɍ ÜǺǪǹzǷǺǷ 490 ǦDZzǹ ȯzÛǣ

ǦǺzĿΣä ǧäǻȒŁŸö ǦĿDZzȯzĿǣşÀȮţä ǦÊǺǺÕţä" ȷäzǺʒ ǨƠ Ǧzzȍzǹ ȹŁ ǺŁõ ǦÊǺǺÕţä ĘǦÛǩ :**Assay** ǦÊǺǺÕţä *Bacillus cereus* (NCTC ǦǹzÔȞöä ÿäÆÅǪèǺǣ Û(155 ǦHǺÔöä Û1ÆŸǑä) "Microbiological assay of antibiotics ÿzĿèǺǩzǦöä ǧǺǺÊǲ Ǧǝǿäá Û6.6 ȹǝǺŒ ǒǺŁǺǣ şǣ Cm10 ţǿà Ȕèş ÛǿǺǦǪǹɍä ȹǵ ǼǝǺȮõ 10320 or ATCC 11778) Ž ǦĿöşá ǥÆǵş 2.0ş 0.2 ƙǣ ǥáǺʒ) ÆèǺǺǹ ÂĿõÀǪǣ ƙŸȮĿè ȹÊõşÆöä Ǽǹ ȯzŸȚş ÛTS(ȯ/ȟ13.6) ƙDZşǿÆĿŢä ǦĿǝǺǺǪ ǦĿŸʒǺǺŸö ŭÛÅŸö ǥÆŁǪȞţä áşÆΣä ǺȚĿz ȷzȮǩ ɍ ȷǕ ȹŁ ǦÊǺǺÕţä Ǧǫá .°ÿ39-35 ǥǿǺȁǵ ǦDZǿÆǣ ǼȒHǺłş Û(Ōǹ 1 Õõ ÆΣä ȷzȮǺ ɍş .ǥǿÆÕţä ǦĿŸʒǺǺöä Ǽǹ %105.0 Ǽǹ Àǯõǔ ɍş %95 Ǽǹ ŌǫǕ estimated potency (P = 0.95) ǥǿÆÕţä ÛǹŸǹ 1 Õõ Ž ƙŸȮĿè ȹÊõşÆöä Ǽǹ ǦĿöşá ǥÆǵş 880 Ǽǹ ŌǫǕ (P = 0.95) ǥǿÆÕţä ǦĿŸʒǺǺŸö ŭÛÅŸö ɃzŸȞöä ÆŁǪȞţä

.ȯzǷǯǺɋä Ǽǹ ǦĿöǺʅä ǦĿǝǺǹŸöä ǥáǺţä ƂǕ ţzDZÀöǺǣ ǦǣzÊȚ

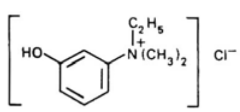
EDROPHONII CHLORIDUM

Edrophonium chloride !ǋīǆǋʒǋþǫīǕɛ ǫīþǋǂ!

$C_{10}H_{16}ClNO$:**Molecular formula** ǦĿǺÂƨä Ǧ8ĿÔöä

201.7 :**Relative molecular mass** ǦĿǦÊǺöä ǦĿǺÂƨä ǦŸǪȮöä

:**Graphic formula** ǦĿǷǺĿǦţä Ǧ8ĿÔöä



:**Chemical name** ȹǝǺĿŁĿȮöä ǈèɍä

Ethyl(*m*-hydroxyphenyl)dimethylammonium chloride;
N-ethyl-3-hydroxy-*N*,*N*-dimethylbenzenaminium chloride; CAS Reg. No. 116-38-1.

.ǦHǝäÀöä ƇÆʒ ÜȒĿǣǕ ȷzŸǣ ɃǿzŸǣ ȧzHÊǹ :**Description** Ȥȍzöä

ǺĿŸŁʒ ǟäşǣ ƘǶ ÜTS (ȯ/ȟ750~) ȯzǷǯǺɋä Ǽǹ ǒäÂDZǕ 5 Žş ǒǺţä Ǽǹ ǺǒÂDZ 0.5 Ž ǟäşǣ :**Solubility** ǦĿǷǺǣşǾöä

.RƘǪǂä Ž ɍş R ÿǿzzǿzŸȮöä Ž

.Diagnostic agent ȮĿÅÎǩ ŌǹǺʒ :**Category** ǦǺÀöä

.öζȒöä ȡɳ ǦȽȶȚǗȽȽǅ ǦŐŸ8ɳ ǦΛşǺǵ Ž ӯζȽφζζşøǼΛqä ǼΛøζŸõ ŞǺǵ Ǽƶ :**Storage** ȡΛÂǺΏöä

REQUIREMENTS ƘǦhǘƱkǩž!ƒ

ȡȝ ǼΛÂΛ ɍş %98.5 ȡȝ ŐŐΛ ɍ Ǻɳ ɁŸȝ ӯζȽφζζşøǼΛqä ǼΛøζŸõ ɃζΏƷ :**General requirement** ӯǺȞöä ǼŸÛΏȶä
.ǦǺǺŎä ǵǻǺȶä ƂǗ ţζǅǺöǺä ǦäζȆȚ Û$C_{10}H_{16}ClNO$ %101.0

:**Identity tests** ȟȊNjNJǁƐ ǀ ƐƥƑǦǶƣƐ

ǺɳǼΛȝ ÛVS (ȯ/ȯζɳ 0.1) ŐΛøζŸõşøǼȽTä Ȓ ƥ Ž Őɳ/ɳŸɳ 0.050 ÂȽõǺΏä ȯζŸǂ ȋ ǺÔΏɳɍä ƵȽù ɃǼǦΛ :A
ɳŸǦΛ ÜǺΏɳζφǺφ 273 ǦäǺȩ ǦǅZζɳ ȯζÛä ǼȽȶȚȝǗ ǼòǺÔΏɳä ÛǺΏɳζφǺφ 350ş ǺΏɳζφǺφ 230 ƙä ǯäζɳɉä ȯäζùǗ Ž ǼȽǺÎΛ
.0.55 ǦäǺȩ äØȽ ǦǅZζȶä ȯζù Ž ǈè1 ǦφǺǺǯä ǦŐǦù ȯŸǹ ȡɳ ȋ ǺȶΏöä

(ȯ/ȯζɳ 0.1) ӯζΛǻζÔöä ǼȽȆõşøǼȽȽ ȯζŸȚ Ž Őɳ/ӯäǺȡşǺȮɳ 10 ÂȽõǺΏä ȯζŸǂ ȋ ǺÔΏɳɍä ƵȽù ɃǼǦΛ :B
240 ǦäǺȩ ǦǅZζɳ ȯζÛä ƙȽȶȚȝǗ ƙòǺÔΏɳä ÛǺΏɳζφǺφ 350ş ǺΏɳζφǺφ 230 ƙä ǯäζɳɉä ȯäζùǗ Ž ǼȽǺÎΛ ǺɳǼΛȝÜVS
ɁŸȝ 0.17ş 0.55 ǦäǺȩ ƙΏǅZζȶä ƙǩǺȽ ƃζÛä ǈè1 ǦφǺǺǯä ǦŐǦù ȯŸǹ ȡɳ ȋ ǺȶΏöä ɳŸǦΛ ÜǺΏɳζφǺφ 294 ǦǅZζȶäş ǺΏɳζφǺφ
.ƃäζΏöä

ȷζǐ ǰΏǺΛ ÜTS(ȯ/ȟ25) ŐΛǼΛǼΣä ǼΛøζŸõ ȯζŸȚ ȡɳ Őɳ 0.05 ȢǺȒΛş ǒǺɳ Őɳ 2 Ž ȟ 0.05 ǟäØΛ :C
.ǺƥɉäƂǗ ǟøǺȓ ɄǅzȆǺǺä

.ŐȮǺΏöä Ʒɳ °ӯ168 ǦäǺȩ ÛøǺȚÔφɍä ǦǅZøǻ :D

General ǦɳǺȞöä ȢäǺȞΏèɍä ǧäøǺǦΏǹä" ȷäζǺȝ ǨƠ ȢζòζȶäA ŐȝǺǺΏöä Őɳ/ɳŸɳ 20 ÂȽõǺΏä ȯζŸǂä ɄÛȞΛ :E
.(121 ǦǶǺÔöä Û1ǼŸŎä) ǧäǼΛøζŸȮŸö ÂȸȶȟŐȝǺǺΏõ "identification tests

.ȟ/ɳŸɳ1.0 ȡȝ ǼΛÂΛ ɍ :**Sulfated ash** ǨŸǺȆȶä ǻǺɳǺöä

ζŸȽõ 0.6 ȡȝ ǼΛÂΛ ɍ) ȒǺǺΛɳ Ȕ8ȓ ǨƠ ȔȽǂä ǵøäǺǵ ǦǅZøǼä ƵǺƶ :**Loss on drying** ƵȽǺǅzΏöǺä ǼŐǺöä
.ȟ/ɳŸɳ 5.0 ȡɳ ǺǯõǗ ǼŐǺΛ ɍ ÜǦȝǺè 24 ǵǼɳ R øζǺȆǺΛöä ǼȽȆõǗ ɄèǺȶȟ ǻζζ (ȨȽǻà ǈŸɳ 5 ǦäǺȩ şǗ ȯǺȮèǺä

.5.0-4.0 ÛŐɳ/ȟ 0.10 ÂȽõǺΏä ȯζŸǂä ǒǺȽǺä ɳŸǦΛ :**pH Value** ǒǺȽǺǦöä ǦȶȽȩ

Ǧəøäǻ ȡɳ Őɳ 5 ȢǺȒΛş ÛǒǺɳ Őɳ 10 Ž ȟ0.1 ǟäØΛ :**Dimethylaminophenol** ȯζǼȽζ ζǼȽɳǗ ŐȽǯȽɳ ɄəǺǺφ
ɁŸȝ ȷǺΏòŸǃä ŐȆ8ǩ .R ӯøζζşøζŸõ Őɳ 20 ǺȶȚǺɳ Őõ ƙΏǺΏä ƙΏȽȶȮä ȍŸǺΏȆΛş ÛTS Û8.0 ǒǺȽǺä ǧäǼ ǧǺǺȆǯ
(ȯ/ȯζɳ 0.1) ӯζΛǻζÔöä ǼȽȆõşøǼȽȽ ȯζŸȚ ȡɳ Őɳ 10 øä ȍŸǺΏȆΛş ÛǒǺɳ Őɳ 10 ǺȶȚǺɳ Őõ ƙΏǺΏä ƙΏȽȶȮä ƃäζΏöä
ǼΛÂΛ ɍ ÜǺΏɳζφǺφ 293 ǦǅZζɳ ȯζÛä ǈè 1 ǦφǺǺǯä ǦŐǦù ȯŸǹ ȡɳ ӯζΛǻζÔöä ǼȽȆõşøǼȽȽ ǦòŸǃ ȋ ǺȶΏöä ǟǺŐΛ .VS
.0.25 ȡȝ

ȣ ǺȒǺ ǕR1 ɄDzŸǯöä ȬɆǬèɉä Ȑƥ ȡȠ Ōȵ 20 Ž ǕǦɆüƺǴRȠ ǦφşàƺȠ Ǖȟ 0.2 ǦǎäǺę ā ǻØǺ :**Assay** ǦÊǺǺŌţä ǺǺǺȞǺş ǕTS ȯƺφǺǯǺǓ/ȡǺǼǼǺǼȮöä ǥǺȶǥ́ ȯƺŸȚ ȡȠ Ōȵ 0.25ş TS ȬɆǬèɉä Ȑƥ/ȨǦǝǺöä ğǺǬɆèǓ ȯƺŸȚ ȡȠ Ōȵ10 Non- ɄǝǺȠŸöä Ǖèƺöä Ž ǥǺǺǺŤţä" ɈäƺǺʒ ǨƠ ȣƺȍƺȠ ƺȽ ǺȶȭVS (ȯ/ȯƺȠ 0.1) ȬǺøƺŸȭǨǦöä Ȑƥ ȯƺŸɄȠ VS (ȯ/ȯƺȠ0.1) ȬǺøƺŸȭǨǦöä Ȑƥ ȡȠ Ōȵ 1Ȯȭ.(142 ǦɄǺȎöä Ǖ1 ǼŸǑä) A ǦȬǺǺǕöä ǼÊɰ Ǖ"aqueous titration .$C_{10}H_{16}ClNO$ ȡȠ ȠŸȠ 20.17 ȕƺǺȮǺ

EMETINI HYDROCHLORIDUM

Emetine hydrochloride ǲĭȾĭǲǯĭǕǫ ȹĭƥǋɨǀǋƥȹĭǀǰ

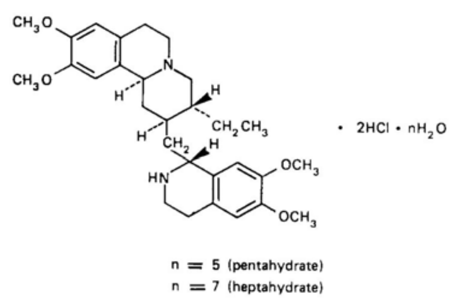
Emetine hydrochloride pentahydrate ǀǫƥȹĭǋǁǫ Ĭ ƨǲǯȹ ǲĭȾĭǲǯĭǕǫ ȹĭƥǋɨǀǋƥȹĭǀǰ

Emetine hydrochloride heptahydrate ǀǫƥȹĭǋǁǫ ĬYǲǴƨ ǲĭȾĭǲǯĭǕǫ ȹĭƥǋɨǀǋƥȹĭǀǰ

$C_{29}H_{40}N_2O_4$, Ü$C_{29}H_{40}N_2O_4$, 2HCl,7H_2O (heptahydrate) :**Molecular formula** ǦɆǺǺÂƨä Ǧȣ ɆÔöä .2HCl,5H_2O (pentahydrate)

.643.6 (pentahydrate); 679.7 (heptahydrate) :**Relative molecular mass** ǦɆǦÊǺöä ǦɆǺǺÂƨä ǦŸǪȮöä

:**Graphic formula** ǦɆφǺɆǦţä ǦȣɆÔöä



:**Chemical name** ɄǝǺɆȶɆȮöä ɭèɍä

Emetine dihydrochloride pentahydrate; 6′,7′,10,11-tetramethoxyemetan dihydrochloride pentahydrate; CAS Reg. No. 79300-07-5 (pentahydrate).
Emetine dihydrochloride heptahydrate; 6′,7′,10,11-tetramethoxyemetan dihydrochloride heptahydrate; CAS Reg. No. 79300-08-6 (heptahydrate).

[illegible] **Description:** [illegible].

[illegible] **Solubility:** [illegible] (~750) [illegible] TS [illegible] R.

[illegible] **Category:** [illegible] Antiamoebic.

[illegible] **Storage:** [illegible].

[illegible] **Labelling:** [illegible].

[illegible] **Additional information:** [illegible] ipecacuanha [illegible] cephaëline [illegible].

REQUIREMENTS [illegible]

[illegible] **General requirement:** [illegible] %98.0 [illegible] %101.5 [illegible] $C_{29}H_{40}N_2O_4, 2HCl$ [illegible].

[illegible] **Identity tests:**

- [illegible] A [illegible] D [illegible] B [illegible] C [illegible] D.

A: [illegible] "Spectrophotometry in the infrared region" [illegible] (43 [illegible] 1 [illegible]). [illegible] RS [illegible] *reference spectrum* [illegible].

B: [illegible] "Related alkaloides" [illegible] A [illegible] D.

ǰǪĀĀ ÜTS ÕĀǿźÀŸÊöä Ȑþ/ÿźĘǭźŋɉä ğäÆĠĘöźŋ ȯźŸŢ ȡŋ Ōŋ 1 ǴÛè ʔŸʒ ǿÀĢǪǹɍä ģǻŋ ȡŋ ŋŸŋ 5 ÀÎĀĀ :C
.ţÀţ ÀȒǹǕ ȷźō

General ǦŋÀȞöä ȣäÀȞǪèɍä ğäǿÀĢǪǹä" ȷäźÀʒ ǨƠ ȣźòźţä B ŌʒÀĀǪöä Ōŋ/ȟ 0.05 ÂĘÕÀǪæ ȯźŸǂä ɄÛȞĀ :D
.(121 ǦȞÀÔöä Û1 ÆŸŎä) ğäÆĀǿźŸȮŸö ÂƀȶȽ ŌʒÀĀǪÕ "identification tests

ƁǕ ţźǅZÀöÀæ ÆÊʒȘ Ōŋ/ŋŸŋ 50 ÂĘÕÀǪæ ȯźŸŢ ŌȶȞǪÊĀ :**Specific optical rotation** Ʉʒ źÀöä ȴÀÔǦöä ÀĀȘÆǪöä

$[a]_D^{20°C}$ = +16 to +19° ǗǦÀÀŎä ģǻţä

.ȟ/ŋŸŋ 1.0 ȡʒ ÆĀÂĀ ɍ :**Sulfated ash** ǨÀŸÊţä ǻÀŋÀöä

ÆĀǿźŸÕȘǿÆĘȽ ÆŌÀĀ ɍ Ü°ÿ105 ģǿäÀǵ ǦǅZǿÆæ ǨæÀǯöä ȷäźöä ʔøǪǵ ȤÀƶ :**Loss on drying** ȤĘÀǅZǪöÀæ ÆŌÀöä
ɄʒÀĢè ƙǪĘɕɋä ÆĀǿźŸÕȘǿÆĘȽ ÆŌÀĀ ɍȘ .ȟ/ŋŸŋ 150 ȡŋ ÀǯÕǕ ɍȘ ŋŸŋ 110 ȡŋ ŌȩǕ ğäǿÆĘŢä ɄèÀȒ ƙǪĘɕɋä
.ȟ/ŋŸŋ 190 ȡŋ ÀǯÕǕ ɍȘ ȟ/ŋŸŋ 150 ȡŋ ŌȩǕ ğäǿÆĘŢä

ÆĘÊÕȘǿÆĘȽ ȯźŸȞŋ ÀĀÀȞĀȘ R ȷźæÀȮöä ÆĘÊÕǕ ɄəÀĀǬ ȡŋ ȯÀǹ ŏÀŋ Ōŋ10 Ž ȟ 0.10 ǡäǾĀ :**Acidity** Ǧȑ źȶΣä
ʔŸʒ ȯźÔȞŸö Ōŋ 0.5 ȡŋ ÀǯÕǕ ÿÀŸĀ ɍ ÜTS ȯźǷÀǯĀǕ/ŌĘǯĘţä ģÀȶǥ ÀȞÎŋ ÿäÆǺǪèÀæ ÛVS (ȯ/ȯźŋ 0.02) ÿźĀǻźÔöä
.(ƂÀŌǨÀæ) ÀȞÎȶŸö ʔÛèźöä ǦÛŌÀöä ȷźō

ǦŌĘȩÀöä ǦŌǦÛöä ǡäÀÎǪèä" ȷäźÀʒ ǨƠ ȣźòźŋ źȽ ÀȶÕ ǿÀĢǪǹɍä ĘǦÛĀ :**Related alkaloids** ǦŏÀÎţä ğÀĘǭźŸǬöä
100 ȡŋ ǰĀÂŋȘ ǦŸȣ8ŋ ģǻȶÕ R1 ÀǾĘŸĘÊöä ǦŋɎȽ ÿäÆǺǪèÀæ Û(84 ǦȞÀÔöä Û1 ÆŸŎä) "Thin-layer chromatography
2 ÛR ȯźǷÀǯĘţä ȡŋ ÿźǅZǵ 5 Ûethylene glycol monomethyl ether R ȡŋ ÀȶǅZǵ 20 ÛR ÿǿźźȘǿźŸȮöä ȡŋ ȴǅZǵ
4 ȡŋ ǦȞĘÀÔöä ʔŸʒ ÀǪöȘÀȮŋ 10 ȤÔÀĀŋ ĘǦÛĀ .ŌÀȞǪŋ ǿźÛÕ R ƙŋɎĘǯĀǕ ɄəÀĀǬ ȡŋ ÀȶǅZǵ 0.5Ș ŏÀţä ȡŋ ÀȶǅZǵ
0.50 Ƀźʒ :(A) ȯźŸǂä ÛR ȯźǷÀǯĘţä ȡŋ ÀȶǅZǵ 99ȘTS (ȯ/ȟ17~) ÀĘǭźŋɉä ȡŋ ÀȶǅZǵ 1 ȡŋ ȤōǿŋǰĀÂŋ Ž ŌĘŏÀŢ
cephaëline ƙŸəÀÀĘÊöä ÆĀǿźŸÕȘǿÆĘȽ ȡŋ ÿäÀȡȘÀȮŋ 10 Ƀźʒ :(B) ȯźŸǂä ÛŌŋ 1 ŌÕ Ž ǿÀĢǪǹɍä ģǻŋ ȡŋ ŋŸŋ
:(D) ȯźŸǂäȘ Ōŋ 1 ŌÕ Ž ǿÀĢǪǹɍä ģǻŋ ȡŋ ÿäÀȡȘÀȮŋ 5.0 Ƀźʒ :(C) ȯźŸǂä ÛŌŋ 1 ŌÕ Ž hydrochlorid R
ȤǅZǪö ÕÀǪǨ ÛǡäÀÎǪèɍä ģǨǅZǵ ȡŋ ǦȞĘÀÔöä ţÂǷ ÆȞæȘ .Ōŋ1 ŌÕ Ž RS ƙǪĘɕɋä ÆĀǿźŸÕȘǿÆĘȽ ŋŸŋ 0.50 Ƀźʒ
15 ģÆŋ °ÿ 60 ǦǅZǿÆŌÀæ ȡǺÊǨȘ ÛTS ÿǿźźȘǿźŸÕ/ǻźĀ ȯźŸȞŋ ǦȞĘÀÔöä æÀǨ Ż ÛğÀĢĀǾţä ÀǺĢǨ ʔøǪǵ ŏäźŢä Ž
A ȯźŸǂä ȡŋ ǰǪĀǨ ǦȞŌæ ǦĀǕ ȷźȮǨ ɍ .(ÀǪŋźǷÀǷ 365) ǦĘǅZÊÀĀǦöä ȧźź ǦȞǹɉä Ž ǡäÀÎǪèɍä ǕÛƯ ȮȞÀĀȘ ÛǦŌĘȩǻ
ȡŋ ģÆǹ ÀǯÕǕ A ȯźŸǂä ȡŋ ǰǪĀǨ ʔÀǹǕ ǦȞŌæ ǦĀǕ ȷźȮǨ ɍȘ .B ȯźŸǂä ȡŋ ǦɗÀĀöä ǦŌźäźţä ǦȞŌǦöä ŌŸǨ ȡŋ ģÆǹ ÀǯÕǕ
.C ȯźŸǂä ȡŋ ǦɗÀĀöä ŌŸǨ

10 ȣÀȒĀ ÛR1 ɄǅZŸǯöä ŌĘǪèɉä Ȑþ ȡŋ Ōŋ 30 Ž ÛǦĘùźǦȒŋ ǦǷȘàźŋ Ûȟ 0.2 ǦääÀȩ ǡäǾĀ :**Assay** ǦÊĀÀŌţä
ȣźòźŋ źȽ ÀȶÕ VS (ȯ/ȯźŋ 0.1) ŌĀǿźŸÕǨǦöä ȐȶШ ÀĀÀȞĀȘ TS ŌĘǪèɉä Ȑþ/ĘǦəÂöä ğÀǪĘèǕ ȯźŸŢ ȡŋ Ōŋ

[illegible] (142 [illegible] 1 [illegible]) A [illegible] "Non-aqueous titration [illegible] 1 [illegible] (0.1/[illegible]) VS [illegible] 27.68 [illegible] $C_{29}H_{40}N_2O_4$, 2HCl.

EPHEDRINUM

Ephedrine [illegible]

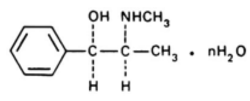
Ephedrine, anhydrous [illegible]

Ephedrine, hemihydrate [illegible]

[illegible] **Molecular formula:** $C_{10}H_{15}NO$(anhydrous); $C_{10}H_{15}NO$, ½ H_2O (hemihydrate)

[illegible] **Relative molecular mass:** 165.2 (anhydrous) [illegible] 174.2 (hemihydrate)

[illegible] **Graphic formula:**



n = O (anhydrous)
n = 1/2 (hemihydrate)

[illegible] **Chemical name:**

(–)-Ephedrine; [*R*-(*R**,*S**)]-α-[1-(methylamino)ethyl]benzene-methanol; CAS Reg. No. 299-42-3 (anhydrous).
(–)-Ephedrine hemihydrate; [*R*-(*R**,*S**)]-α-[1-(methylamino)ethyl]benzene-methanol hemihydrate; CAS Reg. No. 50906-05-3 (hemihydrate).

[illegible] **Description:** [illegible]

[illegible] **Solubility:** [illegible] (~750/[illegible]) TS [illegible]

[illegible] **Category:** [illegible]

[illegible] **Storage:** [illegible]

[illegible] **Labelling:** [illegible]

Additional information: [illegible] 10 [illegible] 1 [illegible]

[illegible] 38 [illegible] 42 [illegible]

REQUIREMENTS [illegible]

General requirement: [illegible] 98.5% [illegible] 101.0% [illegible] $C_{10}H_{15}NO$ [illegible]

Identity tests:

A: [illegible] 0.05 [illegible] (0.1 [illegible]) VS [illegible] 350 [illegible] 230 [illegible] 251 ,257 ,263 [illegible]

B: [illegible] 10 [illegible] 1 [illegible] 0.1 [illegible] (II) (80 [illegible]) TS [illegible] 2 [illegible] 1 [illegible] R [illegible] (~80 [illegible]) TS [illegible]

C: [illegible] 0.05 [illegible] 5 [illegible] (~80 [illegible]) TS [illegible] 4 [illegible] (50 [illegible]) TS [illegible]

Specific optical rotation: [illegible] 2.25 [illegible] 15 [illegible] (~70 [illegible]) TS [illegible] 50 [illegible]

$[a]_D^{20°C}$ = – 41 to – 43°

Chlorides: [illegible] 0.7 [illegible] 2 [illegible] (~130 [illegible]) TS [illegible] 20 [illegible] "Limit test for chlorides [illegible]" ([illegible] 124 [illegible]) [illegible] 0.35 [illegible]

Sulfates: [illegible] 1.2 [illegible] 20 [illegible] "Limit test for Sulfates [illegible]" ([illegible] 1 [illegible] 125 [illegible]) [illegible] 0.4 [illegible]

Sulfated ash: [illegible] 1.0 [illegible]

Water: [illegible] "Determination of water by the Karl Fischer method" [illegible] A ([illegible] 1 [illegible] 145 [illegible]) [illegible] 2 [illegible]

ǑǑՃ ғ Ügåᾶţā ȸȵ ȟ 1 ǦääÀę ўÆÁϘÊՃ ğäøÆŦŢā ȤÔφ ǑȮÎŸö ǦǤÊÅöÅæş .ȟ/ȠŸȵ 10 ȸȝ ŏᾶţā ȜȥϘȚ ÆՃÂՃ ғ Ügåᾶţā ȸȵ
.ȟ/ȠŸȵ55 ȸȝ ÆՃÂՃ ғş ȟ/ȠŸȵ 45 ȸȝ ŏᾶţā ȜȥϘȚ

50.0 ȣᾶȒՃ ÛTS(ȯ/ȟ750~) ȯȥφᾶǯՃɋā ȸȵ Ǒȵ 5 Ž ÛǦŦüȥǦȒȵ Ǧφşàȥȵ Ûȟ 0.5 ǦääÀę ā äØՃ :**Assay** ǦÊՃᾶǑţā
ўäÆÁϘèᾶæ ÛVS(ȯ/ȯȥȵ 0.1) ўȥՃåȥÔöä ÆŦÊÕşøÆŦŁ ȯȥŸȞȵ ÀᾶȞՃş VS(ȯ/ȯȥȵ 0.1) ȬՃøȥŸÕşøÆŦŢā Ȑϸ ȸȵ Ǒȵ
ȠŸȵ 16.52 ùȥᾶǑՃ VS(ȯ/ȯȥȵ 0.1) ȬՃøȥŸÕşøÆŦŢā Ȑϸ ȸȵ Ǒȵ 1 ǑÕ .TS ȯȥφᾶǯՃŰ/ǑŦǯŦţā ğᾶŧǥ ÀȞÎȵ
.$C_{10}H_{15}NO$ ȸȵ

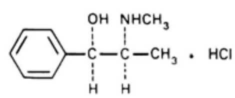
EPHEDRINI HYDROCHLORIDUM

Ephedrine hydrochloride ǄĭϸơĭƵĭǗɛ ơĭϸǋǂǀǋϸơĭǉ

$C_{10}H_{15}NO,HCl$:**Molecular formula** ǦŦᾶՃÂƨā Ǧ8ŦÔöä

201.7 :**Relative molecular mass** ǦŦǦÊՃöä ǦŦᾶՃÂƨā ǦŸϘǑöä

:**Graphic formula** ǦŦφᾶŦǦţā Ǧ8ŦÔöä



:**Chemical name** ȗəᾶŦŧŦǑöä ǉèғā

(–)-Ephedrine hydrochloride; [*R*-(*R**,*S**)]-α-[1-(methylamino)ethyl]benzenemethanol hydrochloride; CAS Reg. No. 50-98-6.

.ǦȞəäÀöä ǅÆȝ ÜȐŦæŰ ȷȥŸæ ɃøȥŸæ ȧȥȞÊȵ şŰ ȷȥŸöä ǦƺÆȝ ğäøȥŸæ :**Description** ȤòȥöäŽ ȸÆǄ ȷᾶæşØöä ǴŦȞì ÜTS (ȯ/ȟ750~) ȯȥφᾶǯՃɋā Ž ā äşæ ÜöÅȵ öäÂǄŰ 4 Ž ā äşæ :**Solubility** ǦŦφᾶæşØöä
.R ƘϘǂā Ž ȸŦŸŧȝ ā äşæ Ƙȡ ÜR ÿøȥȥşøȥŸǑöä

.ȥæÀŸö åᾶȒȵ öäşå :**Category** ǦᾶÀöä

.öȥȒöä ȸȵ ǦŦŧȚ ÛȸÆŦǄ ǦǑŸ8ȵ ǦՃşᾶǥŽ ȸՃøÆŦᾶՃɋā ÆՃøȥŸÕşøÆŦŁ Şᾶǥ Æƶ :**Storage** ȸՃÂÁϘöä
.öȥȒŸö ô ÀȞϘöä ÆᾶȝȸᾶÕäå ȸՃøÆŦᾶՃɋā ÆՃøȥŸÕşøÆŦŁ ȷȥö ǴǦÔՃ :**Additional information** ǦŦȥᾶȓŰ ğᾶȠȥŸȞȵ

REQUIREMENTS ƘǦŲƱŔŽ!ƒ

[illegible] **General requirement:** [illegible] 99.0% [illegible] 101.0% [illegible] $C_{10}H_{15}NO, HCl$ [illegible].

[illegible] **Identity tests:**

A: [illegible] 0.05 [illegible] 230 [illegible] 350 [illegible] 251 [illegible] 257 [illegible] 263 [illegible] 1 [illegible] 0.37 [illegible] 0.48 [illegible] 0.36 [illegible].

B: [illegible] 10 [illegible] 1 [illegible] 0.1 [illegible] (II) [illegible] TS (80~) [illegible] 2 [illegible] 1 [illegible] TS (80~) [illegible].

C: [illegible] 0,05 [illegible] 5 [illegible] TS (80~) [illegible] 4 [illegible] TS (50) [illegible].

[illegible] **Melting range:** 217 – 220 °[illegible].

[illegible] **Specific optical rotation:** [illegible] 50 [illegible] – 33.0 to -35.5° $[a]_D^{20°C}$ = .

[illegible] **Sulfates:** [illegible] 0.050 [illegible] 40 [illegible] 1.5 [illegible] TS (70~) [illegible] 1 [illegible] TS (50) [illegible] 10 [illegible].

[illegible] **Clarity and colour of solution:** [illegible] 1.0 [illegible] 10 [illegible] opalescence standard [illegible].

[illegible] **Sulfated ash:** [illegible] 1.0 [illegible].

[illegible] **Loss on drying:** [illegible] 105°[illegible] 5.0 [illegible].

[illegible] **Acidity and alkalinity:** [illegible] 1.0 [illegible] 10 [illegible] .01 [illegible] TS [illegible] 0.1 [illegible] VS (0.1) [illegible] 0.1 [illegible] VS (0.1) [illegible].

[illegible] **Assay:** [illegible] 0.2 [illegible] 10 [illegible] TS [illegible] 50 [illegible] 1 R [illegible] TS [illegible]

A [illegible] "Non-aqueous titration [illegible] 0.1) [illegible] 20.17 [illegible] 0.1) [illegible] 1 [illegible] (142 [illegible] 1 [illegible]) $C_{10}H_{15}NO,HCl$.

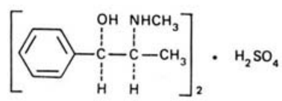
EPHEDRINI SULFAS

Ephedrine sulfate [illegible]

$(C_{10}H_{15}NO)_2,H_2SO_4$:**Molecular formula** [illegible]

428.5 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

(–)-Ephedrine sulfate (2:1) (salt); [*R*-(*R**,*S**)]-α-[1-(methylamino)ethyl]benzenemethanol sulfate (2:1) (salt); CAS Reg. No. 134-72-5.

[illegible] :**Description** [illegible].

TS (750~) [illegible] :**Solubility** [illegible].

[illegible] :**Category** [illegible].

[illegible] :**Storage** [illegible].

[illegible] :**Additional information** [illegible].

REQUIREMENTS [illegible]

[illegible] %98.0 [illegible] :**General requirement** [illegible] %101.0 [illegible] $(C_{10}H_{15}NO)_2,H_2SO_4$ [illegible].

:Identity tests [illegible]

[illegible] :A [illegible] 1.0 [illegible] 230 [illegible] 350 [illegible] 251 [illegible] 257 [illegible] 262 [illegible] 0.61 [illegible] 0.76 [illegible] 0.61 [illegible] 1 [illegible]

:B [illegible] 10 [illegible] 1 [illegible] 0.1 [illegible] (II) (80) TS [illegible] 2 [illegible] 1 [illegible] TS (80~) [illegible]

:C [illegible] 0.05 [illegible] 5 [illegible] TS (80~) [illegible] 4 [illegible] TS (50) [illegible]

:D [illegible] 20 [illegible] A [illegible] General "identification tests [illegible] (123 [illegible] 1 [illegible]).

:E [illegible] 245 [illegible].

:Specific optical rotation [illegible] 50 [illegible] $[a]_D^{20°C}$ = - 33.5 to –32.5° [illegible].

:Chlorides [illegible] 0.20 [illegible] "Limit test for chlorides [illegible] (124 [illegible] 1 [illegible]) [illegible] VS (0.02) [illegible] 1.4 [illegible] 0.40 [illegible].

:Clarity and colour of solution [illegible] 1.0 [illegible] 10 [illegible] opalescence standard TS2 [illegible].

:Sulfated ash [illegible] 1.0 [illegible].

:Loss on drying [illegible] 105 [illegible] 20 [illegible].

:Acidity and alkalinity [illegible] 1.0 [illegible] 10 [illegible] 0.1 [illegible] TS [illegible] 0.1 [illegible] VS (0.1) [illegible] 0.1 [illegible] VS (0.1) [illegible].

ÆǁøǫŸõ ȸŋ ȟ 3 Ƃǟǫǵ Ȣ Ȧ Ȓǁş ÛöȦŋ Ōŋ 10 Ž ÛǴǁüǫǴȒŋ Ǵǭşàǫŋ Ûȟ 0.3 Ǵǟǟ Ȧę ā ǟØǁ :**Assay** ǴÊǁȦŌţǟ
ÒŸǺǫÊǁş VS (ȯ/ȯǫŋ1) ÿǫǁåǫÔöǟ ÆǁÊõşøÆǁȽ ȯǫŸȚ ȸŋ Ōŋ 5 Ȣ ȦȒǁ ØǝÆǁȝ ÛȯǫŸ ǂǟ ţ ȦǴ ì q R ÿǫǁåǫÔöǟ
ȯǫŸȚ ȸŋ Ōŋ 10 øǟ ÿøǫǫşøǫŸȮöǟ ğ ɍ ȦÊǁȡ ǰ ǁȦŋ ŌÊȢǂ .R ÿøǫǫşøǫŸȮöǟ ȸŋ ÛŌŋ 25 ȦǁŤȦŋ Ōõ ÛÿǫǄǵ ǴȞǟøüǟ
Ōŋ 10 Ȝŋ ȖǝȦţǟ ŌǁÊȢöǟ ȯǫŸȚ ŋȒ Ƹ .R ÿøǫǫşøǫŸȮöȦǟ ȜǟÎŋ ɀŌȦȟ ȸÛę ƎȜ Ǵ ì Ȧǁş ÛȜǴÎţǟ R ÿǫǁåǫÔöǟ ÆǁøǫŸõ
ȀǁȦȞǁş TS ȯǫǭȦǯǁǗ/ŌǁǯǁţǟǥȀȶǵ ȯǫŸȚ ȸŋ Ōŋ 0.25 Ȣ ȦȒǁş .ǴǁÊǁǝȀöǟ ÿøǫǫşøǫŸȮöǟ Ǵ ò Ÿ Ȣ ȦȒǁş R ÿøǫǫşøǫŸõ
Ȕèǫöǟ Ž ǥȀǁȦȞţǟ" ǰǟǫǁȝ ǨƠ Ȣ ǫ ò ǫŋ ǫȽ Ȧȶõ ÛVS(ȯ/ȯǫŋ 0.1) ǰ ȦÊõǫǁǻ/ŌǁøǫŸõǨǴöǟ Ȓ þ ȯǫŸǶŋ
ǰ ȦÊõǫǁǻ/ŌǁøǫŸõǨǴöǟ Ȓ þ ȸŋ Ōŋ 1 Ōõ .(142 ǴǶȦÔöǟ Û1 ÆŸŎǟ) A ǴŌǁȀÛöǟ Û"Non-aqueous titrationȖǝȦŋŸöǟ
.($C_{10}H_{15}NO$)$_2$, H_2SO_4 ȸŋ Ƞ Ÿŋ 21.43 ȕǫȦȮǁ VS(ȯ/ȯǫŋ0.1)

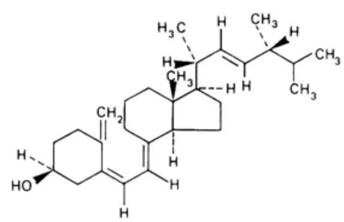
ERGOCALCIFEROLUM

Ergocalciferol üǋþǐƨǐƨǁǁǀǋȜþǟ

$C_{28}H_{44}O$:**Molecular formula** ǴǁȦǁÂƨǟ ǴȢǁÔöǟ

396.7 :**Relative molecular mass** ǴǁǴÊǁöǟ ǴǁȦǁÂƨǟ ǴŸǬȮöǟ

:**Graphic formula** ǴǁǭȦǁǴţǟ ǴȢǁÔöǟ



:**Chemical name** ȖǝȦǁȶǁȮöǟ ǉèɍǟ

(5*Z*,7*E*,22*E*)-9,10-Secoergosta-5,7,10(19),22-tetraene-3β-ol;
24-methyl-9,10-secocholesta-5,7,10(19),22-tetraene-3β-ol; CAS Reg.
No. 50-14-6.

.D_2 ƙŋȦǬǁǫ :**Other name** Ȁń ǿǟ ǉèɍǟ

şǕ ȒǁǟǕ ǰǫŸǟ Ƀøǫǟ ȧǫǶÊŋ şǕ ÆǵȦÎöǟ ȀȦòǬǿ ā øȦȓ ǰǫŸǟ şǕ ǰǫŸöǟ ǴƹÆȝ ğ ǟøǫŸǟ :**Description** Ȥòǫöǟ
.ǁǴǁȀŎǩ ǴǶǝǟȀöǟ ȻÆȝ şǕ ǴǶǝǟȀöǟ ȻÆȝ ÜÆǵȦÎöǟ ȀȦòǬǿ ā øȦȓ

R ÿøźźşøźŸÒöä ş TS (ȯ/ȟ 750~) ȯźφÅ̌ǯǺqä Ž JÅæşØöä Àǵ ÜŏÅţä Ž ÅÈŸȶȝ JÅæşØöä ƇÆȝ :**Solubility** ǦȄφÅæşØöä
.R ƘǪɟäş R JźǪÈèɟäş

.antirachitic Æȟ̀Àöä åÅȒɳ ÛƙɳÅǪȄź :**Category** ǦÅÅöä

ƿÅÅɳ Ž ŌȒÅţä ȡɳ ÛöäźȚŸö ȽȄǪõ źÜ ɂŸȝ ǦŌŸȣɳ ǦÅşÅǵ Ž ȯşƘÅȄÊöÅõźȡøqä ȘÅǵ Æȥ :**Storage** ȡÅÂÅ̋Ǫöä
.°ÿ 8ş 2 ƙæ ǥøäÀǵ ǦǱźøÆæ ǦφÂǕş ŏźȒöä ȡɳ ǦȄȶȚ ÛƙǱźşÀǪÅöä Ōǯɳ Ûinert ŌɳÅǹ ɃźǱ

Ž ɂøǪǵ ÛōöøÆǪÅş .Ǧæźù̀ÀöÅæş ŏäźTÅæ ȯşƘÅȄÊöÅõźȡøqä ÀǪüǪÅ :**Additional information** ǦȄźÅȓÜ ǧÅɳźŸȞɳ
.ɂŸȝɟä ǥøäÀΣä ǧÅǱźøå ÆÅȝ ţÀèÜ ŌȮÅǪöä JźȮÅş ÛɃźƨä ƿÅÅţä Ǧæźù̀Àö ôÀȞǪöä ÆÅȝ ÅȄȥøÆǩ Ûöźȓöä āÅȄȡ

REQUIREMENTS ƘǦȟǚƘȟź!ƒ

:**Identity tests** ȟȉǋǇɛ l ɛþƑǴɈɛ

ƘƠ ǦȞ̀Ìɟä ǦŌÛÅɳ Ž ȖəźȒöä ȤȄÛöä âÅȄę" JäźÅȝ ƘƠ ȣźòźɳ źȴ ÅȶõÒȞÅöä ʔ̀Àȥ :A
ǦȞ̀Ìɟä Ž îÅÔǪɳɍä ȤȄù ȨæÅÛǪÅ .(43 ǦȞÅÔöä Û1 ÆŸǑä) "Spectrophotometry in the infrared regionöäÀȶΣä
reference spectrum ȖȞǱÀţä ȤȄÛöä ȝɳ şÜ RS ȯşƘÅȄÊöÅõźȡøqä ȡɳ ǰÅÅöä ȤȄÛöä ȝɳ öäÀȶΣä ƘƠ
.ȯşƘÅȄÊöÅõźȡøȒö

ŌÅøźÅŸÊöä ȐÞ ȡɳ Ōɳ 5 øØɰ Ōɳ 1.0 ƂÜ ȣÅȒÅ .TS (ȯ/ȟ 750~) ȯźφÅ̌ǯÜ Ōɳ 10 Ž ɳŸɳ 2 ǦæäÀę āäØÅ :B
.(ÀÅòÜ ÅȄφźö ȖÛȞÅ ɃØöä Ûcolecalciferol ȯşƘÅȄÊÅÒȄŏźÒöä ȡȝ ÅÂȄȄǪ) ÀþÜ Jźö ǰǪÅÅ ÜǯÂƹşTS (ȯ/ȟ 750~)
ǦæäÀęş R ŌȄǪȄèɟä (ŏÅɳ Ÿæ) ÆÅøÆȄǢÜ ȡɳ Ōɳ 0.5 ǦæäÀę ȣÅȒÅş R ÿøźźşøźŸÒöä ȡɳ Ōɳ 5 Ž ɳŸɳ 5 āäØÅ :C
ȖǱÊÅÅǦöä ƂÜ ÀþɟäȡɳǥÀ̀ÌÅǦɳ ȯźŸɫä Jźö ȯÅÉǦǪÅ ÜǱÆȄǱ ȒȒƸ .TS (ȯ/ȟ1760~) ŌÅøźÅŸÊöä ȐÞ ȡɳ Ōɳ 0.1
.ȡõäÆöä ÀȒǹɟä ƂÜ ÅƘǹÜş ȧøàɟä ƂÜ Ż

ȯźŸȚ ȡɳ Ōɳ 4 ȯźŸɫä äØȽ ȡɳ Ōɳ1 ƂÜ ȣÅȒÅ .R JÅǯÜøźŸÒÅÆöä ȡɳ Ōɳ 40 Ž ɳŸɳ 1 ǦæäÀę āäØÅ :D
.ÅȄŸÀφÀę ǰÅøÆǪöÅæ ǴǦÔÅ ɃØöä ÛƂÅÕǨÅæ JźŸ ǰǪÅÜantimony trichloride TS

.ȨǦÊɳ ȤȄÀθ şÜ ȨȞè JşǻǦȟȟȟ Û°ÿ117–112 :**Melting range** øÅȚÔφqä ȯÅƒ

ȡɳ ǦȄźÅõ ǦȄȶõ Ž ƙǺÊǨ Jşǻş ǦȝÀÊæ ȟ 0.2 āäØÅ :**Specific optical rotation** ȖȝźÅöä ɃÀÔǦöä ÀÅşÆǪöä
ȡɳ ǦŌȄęǻ 30 ȯŸǹ ɃÀÔǦöä ÀÅşÆǪöä ȡȄȞÅ .Ōɳ 25 øÆŌæ ȽǱǵ ŏÅÛȝq TS(ȯ/ȟ750~) ÆȄȽÆöɟä ȡɳ ƂÅʅä ȯźφÅ̌ǯÅqä
. $[a]_D^{20°C}$ = + 103 to +107° ÜƘȒȞǪöä

ȡȝ ÆÅÂÅ ɍş %95.0 ȡȝ ŌŌÅ ɍ Åɳ ɂŸȝ ȯşƘÅȄÊȄÅõźȡøqä ɃźǪȝ :**General requirement** ÿÅȞöä ÆŸÛǪţä
.$C_{28}H_{44}O$ ȡɳ %105.0

Thin-layer ǦŐĘǕÀöä ǦŐǦÛöä ā äÀ Î ()èä" ȷäζΆȝ ǨƠ ȣζòζɳ ζȽ Àʈõ øÀǦ()ǹɍä ȥÀƶ :**Ergosterol** òʂǨ()èζɖøǗ

ŎʈǨ()ÊΛ ŏÀĦ()ɳ øζÛõʂ ÛǦŸǿȣɳ ǥåÀʈõ R1 ÀÓĘŸĘÊöä ǦɳŸȽ ÿäǼÅ()èÀæ Û(84 ǦĦÀÔöä Û1 ǼŸŎä) "chromatography ȡɳ ȠŸɳ 0.10 ǰΛÂʈä Ƀζʒ ÛR ǼĘÊõʂǨǦöä ȡɳ ƃÀʅä Ǩ()ɉäʂ R ȷäÀÓȽζŸÓĘÊöä ȡɳ ǦΛʂÀÊ()ɳ ÿζǄζǵ ȡɳ ǰΛÂɳ ǥÀȒǂä ǦĘöÀ()öä ŎĘöÀǂä ȡɳ À()öʂÀÓɳ 10 ǦĦĘÀÔöä ɁŸȝ ŸÔÀΛɳ ȨǦÛΛ.Ŏɳ 1 Ŏõ Ž butylated hydroxytoluene R butylated ȡɳ ȠŸɳ 0.10ʂ squalane ȡɳ ȠŸɳ 10 ɁŸȝ ɃʂÀΣä R ȷÀǯΛǗ øζŸÓΛǼöä ȡɳ ǰΛÂɳ Ž òÀʈǨ()èɍä ŎǦę ǥÀȉÀǦɳ Ƀζʒ :(B) òζŸǂä ÛŎɳ 1 Ŏõ Ž øÀǦ()ǹɍä ǥåÀɳ ȡɳ ȟ 0.050 Ƀζʒ :(A) òζŸǂä :Ŏɳ 1 Ŏõ Ž hydroxytoluene R Ž ergosterol R òʂǨ()èζɖøɋä ȡɳ ȠŸɳ 0.10 Ƀζʒ :(C) òζŸǂä ÛŎɳ 1 Ŏõ Ž RS òʂǨÀÊĘöÀõζɖøɋä ȡɳ ȟ0.050 ƙöζŸǂä ȡɳ ÿζǄζΣä òåÀǨ()ɳ ǰΛÂɳ ȡɳ ȷζÓ()Λ ɃØöä (D) òζŸǂä ȡɳ À()öʂÀÓɳ 20 ǦĦĘÀÔöä ɁŸȝ ŸȒΛǗ ȨǦÛΛ ÜŎɳ 1 Ŏõ ǫŸ() æÀǩʂ öäζȚä Ž ȤǄ()ö ŏÀ()ǩ Û ā äÀ Î ()èɍä ǥǨǄζǵ ȡɳ ǦĦĘÀÔöä ʈÂɸ ǼĦæʂ .ÿŸȚöä Ž ǦĦĘÀÔöä ŏÀ()ǩ .Cʂ B .øÀȚΛöä öζȒæ ā äÀ Î ()èɍä ǙÛǗ ǑĦÀΛ Ż ÛȨəÀęå 4-3 æÀöä ǼǨæ ÀȚ()ΛΛ .antimony trichloride TS òζŸĦɳ ǧäÀɳ

ʒęζʈä Ž Ȩζäζ()ǩ ÀŒǗ ÜɄøÀæ ȷζŸæ ǴǦÔǩ Ż ƃÀŎǨÀæ – ÀÀòǗ ȷζŸæ ǦΛäǼǦöä Ž A òζŸǂä ȡɳ ǦΘÀΛöä ǦĘÊĘəÀöä ǦǨŎǦöä ȷζÓǩ ŎĘŸŎæ ŎęǗ R_f ǦʈĘę ǧäæ A òζŸǂä ȡɳ ǰ()ǍǨ ǦĘǄÊÀΛæ ǦǨŎæ ǦΛǗ ȷζÓǩ ɍ .B òζŸǂä ȡɳ ǦΘÀΛöä ŎŸǩ ʒɳ ǥǼÎöäʂ ÀȚȚʈäʂ ɃǗ A òζŸǂä ȡɳ ǰǨÀΛöä ā äÀ Î ()èɍä ǙÛǗ ÀȚȚǂ ɍ .C òζŸǂä ȡɳ ǦΘÀΛöä ǦǨŎǦöä ȡɳ ǥǼȉ ÀǯõǗ ǦĘÊĘəÀöä ǦǨŎǦöä ŎŸǩ ȡɳ ǙÛǗ ÀȚȚǂ B Àɳ ȒΣÀò øÀǦ()ǹɍä ǼǨǂ ɍʂ .Cʂ B ƙöζŸǂä ȡɳ ƙΘÀΛöä ā äÀ Î ()èɍä ɄÛÛǗ ʒɳ ǦɸøÀŎʈÀæ ǦĘζÀȑǗ ʒŎæ .ǴȑäʂζǗ ɁŸȝ ƙ()ŸÔÀΛɳ ƙ()ǨŎæ D òζŸǂä ȡɳ ǰǨÀΛöä ā äÀ Î ()èɍä

ǼĘȽǼöɉä ȡɳ òÀǹ òζɸÀǯΛǗ Ŏɳ 10 Ž ȟ0.10 ā äØΛ :**Reducing substances** (ǦǨǄζÀʈä) ǦǺȦ()Åʈä åäζʈä ǼĘÊõʂøǼĘȽ òζŸȚ ȡɳ Ŏɳ 0.5ʂ TS òζɸÀǯΛǗ/ÿζĘöʂàäÀ()()öä Ǧęøà òζŸȚ ȡɳ Ŏɳ 0.5 ȣÀȒΛ ÛTS (ò/ȟ750~) .R ɄǄζŸǯöä ŎĘ()èɉä ȐƥȡɳŎɳ 1 ȣÀȒΛ Ż ȒɳÀ() ȨəÀęå 5 ǥǼɳ øäÀÕ()èŸö ŏÀ()Λ .TS òζɸÀǯΛǗ/ÿζĘɸζɳǗ ŎĘǯĘɳäÀ()()öä òζŸȚ ɁŸȝ ǦΛʂÀΣä ǼΛØʈä ǥǨǄζǵ ŎäÀŎɳ À()ɳζɸÀɸ 525 ǦäÀę ǦǄζɳ òζÛæ ȴè1 ǦɸÀÅǯæ ǦŐǦù òŸǹ ȡɳ î Àʈ()öä â ÀŐΛ ȡɳ ɜõǗ î Àʈ()öä ȷζÓΛ ɍ .ÀȚÊÀɸ ǦŐΛÀÛöÀæ TS (ò/ȟ750~) ǼĘȽǼöɉä ȡɳ ƃÀʅä òζɸÀǯΛɋä ȡɳ Ŏɳ10 ǦȥÀĦɳ ÀȒȚ òζɸÀǯΛɋä Ž hydroquinone R ȡɳ Ŏɳ/ÿäÀɖʂÀÓɳ 0.2 Ƀζʒ òζŸȚ ȡɳ Ŏɳ10 ʒɳ ǦĘŸʈǨöä ǥåÀʒǗ ȡɳ ǰǨÀΛöä î Àʈ()öä ǼĘȽǼöɉä ȡɳ ƃÀʅä .TS (ò/ȟ750~)

òζɸÀǯΛɋä ȡɳ ǦĘζÀõ ǦĘʈõ Ž ÛǦĘùζǦȒɳ ǦɸʂàζɳÛȟ0.05 ƙÅÊǨ ȷʂåʂ ǦΛÓʈʈä ǦʒÀÊöÀæ ā äØΛ :**Assay** ǦÊΛÀŐʈä .ȼÊÀɸ ǼΛØʈÀæ Ŏɳ 250 ƃǗ òζŸǂä äØȽ ȡɳ Ŏɳ 5.0 ȤÀƸ ÜŎɳ 100 öÀÛʒɋ TS (ò/ȟ750~) ǼĘȽǼöɉä ȡɳ ƃÀʅä ǦäÀę ǦǄζɳ òζÛæ ȤÀÅʈä òζŸǂä ȡɳ ȴè1 ǦɸÀÅǯæ ǦŐǦù òŸǹ ȡɳ ǨȒĦ()öä ȡɳ ǦŐĘęå 30 ǥǼɳ òŸǹ î Àʈ()öä â ÀŐΛ ǦöÀ Î ʈÀæ î ζĦÀɳ ÛRS òʂǨÀĘÊöÀõζɖøǗ ʒɳ ǦɸøÀŐʈÀæ ǦòζĦÀʈä ǥÀʈä Ž $C_{28}H_{44}O$ øäǼŎɳ ǼÊĦɫ .À()ɳζɸÀɸ 265

.0.03 ± 0.48 ƟǶDZÀţǟ ȯȥŶĦuŧŶō ÛǦÅÅÖǣ ÄǢĦţǟ ƟǝȥȒöǟ ȤĘÛöǟ ȃÅĘǬŋ Ž Û ȋ ÅŧǬöǟ ȷȥÖÅ ȷÜ Ǽƶ .ȸŋǟÂǬöǟȘ

ERYTHROMYCINUM

Erythromycin ǅȋƨȋDZǈƥǨȋƥƋ

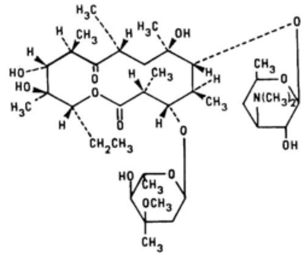
streptomyces ȸŋ ɃØǟǿØöǟ ȀĦǣ ȥʃ ȸŋ ǰǬǼ ǻǟȥŋ ȸŋ ǲƶÂŋ ƙÊĘŋȘÀǮÅǿqǟ ǼĦÅ :**composition** ǼĘÕÀǬöǟ .CȘ B ƙÊĘŋȘÀǮÅǿqǟ ȸŋ ÕęÜ ǦĘŧȭ ȝŋ A ƙÊĘŋȘÀǮÅǿqǟ ȥȽ ǰÅÂŧŶō ƟÊĘǝÀöǟ ȷȥÖţǟȘ .*erythreus*

• ǧÅĘÛĦţǟ ǥǻǿǟȥöǟ :ÅÅȽ ČǮ8ĘÔöǟ ÛǦĘÅÂƨǟ ǦŶǪÖöǟ ǦĘÅÅÂƨǟ ÛǦĘǦÊÅöǟ ȴèɍǟȘ ƟǝÅĘŧĘÖöǟ ǻǟȥĦǨ ƂÜ ƙÊĘŋȘÀǮÅǿqǟ *A* .ÜÖȥ

ǦĘÅÅÂƨǟ ČǮ8ĘÔöǟ **Molecular formula:** $C_{37}H_{67}O_{13}$

ČĘǦÊÅöǟ ǦĘÅÅÂƨǟ ČŶǪÖöǟ **Relative molecular mass:** 733.9

ČĘǬÅĘǦţǟ ČǮ8ĘÔöǟ **Graphic formula:**



ƟǝÅĘŧĘÖöǟ ȴèɍǟ **Chemical name:**

[3*R*-(3*R**,4*S**,5*S**,6*R**,7*R**,9*R**,11*R**,12*R**,13*S**,14*R**)]-4-[(2,6-Dideoxy-3-*C*-methyl-3-*O*-methyl-α-L-*ribo*-hexopyranosyl)oxyl]-14-ethyl-7,12,13-trihydroxy-3,5,7,9,11,13-hexamethyl-6-[[3,4,6-trideoxy-3-(dimethyl-amino)-β-D-*xylo*-hexopyranosyl]oxy]oxacyclotetradecane-2,10-dione; CAS Reg. No. 114-07-8.

ȤǒȥŶǟ **Description:** ǧǻǿȥŶǣ ȘÜ ȧȥĦÊŋ ȷȥŶǣ ȒĘǣÜ ÄÅǒÜ ȋÅǵǥǼÜ ČĦǝǟÀöǟ ȻƎȝ ȘÜ ČĦǝǟÀöǟ ȻƎȝ .ǼǦÅÅÖǩ

ČĘǬÅǣȘØöǟ **Solubility:** ǟ ǟȘǣ Ž 1000 ȸŋ ǒÂDZ ȸŋ ǒÅţǟ ȸÖōȘ ÕęÜ ČĘǬÅǣȘǣ Ž ǒÅţǟ ÜøÅƩǟ ǼǵǺ ǟȘØöǟ ȷÅǣȘ Ž ƙÊĘŋȘÀǮÅǿqǟ ȯȥǬÅǮÅqǟ .R ǱØȥȥȘØȥŶÖöǟȘ R ƘǬǰǟȘ TS (ȯ/ȟ750~)

ǦÅÅǟ **Category:** ǻǟȘ ǻÅȒŋ ǅȥŶǟÀDZŶō ȴĘǬǟ.

ǦǟÂÅǬöǟ **Storage:** ǼƶȘ ǼǺ Ž ƙÊĘŋȘÀǮÅǿqǟ ȘÅǥ ČŶǦǥÜǥ ȘǮÅÖǥ ǦĘŧȚ ȸŋ ȒöǟǦ .ǒȥȒöǟ

.hygroscopic ǦǤùǍǪÊɳ ǥǻɳ ƙÊǇɳʂǍǰǺǿq **:Additional information** ǦǇȥǺȓǕ ǧǺɳȥŸȞɳ

REQUIREMENTS ƘǦǶȢǨ!ƒ

1 Ǭõ Ž ǦǇşǻ ǥǼǵş 870 ȸɜ ǬǾɼǺɳ ʔŸɜ ƙÊǇɳʂǍǰǺǿq Ƀȥʠʒ **:General requirement** ȳǺȞ ǼŸÛǪʈ
.ǦǝǺɳƳ ǥǻʈ ƂǕ ţȥǄǍǾǺ ǦȥÊƮ ÛɳŸɳ

:Identity tests ŀǓǇǷǁ ŀ ƐþƑǴǁƐ

• ȸǬʢ B ǧǿǺǪǹɼ ʂǕ ȻǻǺǺɳ A ǿǺǪǹɼ ȨǄǤÛǨ .Dş Cş B

ǨǪǶ ǦȞȉɉ ǦǬÛǺɳ Ž ɄǝȥȒ ȤǇÛ ȃǺǇę" ɉȥǺɜ ǨǪǶ ȣȥȍȥɳ ȥȽ ǺȶȬ ǸǶǺ ȨǤÛǺ :A
ǦȞȉɉ Ž ȋǺǬǪɳɼ ȤǇù ȨǺÛǪ .(43 ǦǶǺǬ Û1 ǼŸǬ) "Spectrophotometry in the infrared region ǬǺȶΣ
.ƙÊǇɳʂǍǰǺǿȒ *reference spectrum* ɄǶǄǺʈ ȤǇÛ ɜɳ ʂǕ RS ƙÊǇɳʂǍǰǺǿq ȸɳ ǰǨǺ ȤǇÛ ɜɳ ǬǺȶΣ ǨǪǶ
ɄǿǺ ɉȥǒ ǰǪǺ ÛȤÛŸ ȒȢş TS (ȯ/ȟ 1760~) ǬǺǿȥǺŸÊ Ȓþ ȸɳ Ǭɳ 2 ǿǼǬɳ Ǭɳ 5 ƂǕ ȣǺȒǺ :B
.Ǻþȉ ƂǕ ȁǿǺȓ

ɉȥǒ ǰǪǺ ÛTS (ȯ/ȟ 420~) ǬǺǿȥŸõşǿǼǇT Ȓþ ȸɳ Ǭɳ 2 ȣǺȒǺş R ɉȥǪǇèǕ Ǭɳ 2 Ž ɳŸɳ 3 ȁǿǾǺ :C
ǦǬǤù ɉȥŸǪǨ ÛȒȢş R ȳǿȥȥşǿȥŸõ Ǭɳ 2 ȣǺȒǺ .Ȩɳǩǿ ɄǿǪȥǄǿȉǺ Ǻþȉ ƂǕ Ž Ǻþȉ ƂǕ ȯǼǤǪ ɃǾǿ ÛƂǬǨǺ
.ƆǿȥǄǿȉǺ ȳǿȥȥşǿȥŸǑǿ

.ǺþǕ ɉȥǒ ǰǪǺ ÛɄǝǺɳ ȳǺþ Ž ȸǺÊǺş Xanthydrol ȯȥŸƮ ȸɳ Ǭɳ 5 ǿǼǬɳ ɳŸɳ 5 ƂǕ ȣǺȒǺ :D

ţşǺǿǺɳ ȯȥǺǰǺq Ž Ǭɳ/ɳŸɳ 20 ǺǇõǪǪ ȯȥŸƮ ǬȶǶǪÊǺ **:Specific optical rotation** Ʉʒȥǿ ɃǺǬǤǿ ǺǺşǼǪǿ
– 71 to -78° ÛǦǇǺɳƳǿ ǥǻʈ ƂǕ ţȥǄǍǾǺ ǼÊƠş ÛǺşǼǪǿ ǦǺşǿà ȁǺǬǨ ÛǦǬǇęǻ 30 ǥǼɳ ǿǺǬǪèŸǿ õǪǺ ÛR ǿǺʈ
. $[a]_D^{20°C}$ =

.ȟ/ɳŸɳ 2.0 ȸɜ ǼǺǺ ɼ **:Sulfated ash** ǨǺŸÊʈ ǻǺɳǍǿ

Determination of water by ǍȊǇȥ ȯǿǺõ ǦǬǍÛǺ ǿǺʈ ƙǇǨ" ɉȥǺɜ ǨǪǶ ȣȥȍȥɳ ȥȽ ǺȶȬ ȸǇǺ **:Water** ǿǺʈ
ʔȥǪƮ ǼǺǺ ɼ Û ǥǻʈ ȸɳ ȟ1 ǦǿǺę ȳǿǼǺǪèǺ Û(145 ǦǶǺǬ Û1 ǼŸǬ) A ǦǬǍÛǺ Û"the Karl Fischer method
.ȟ/ɳŸɳ 100 ȸɜ ǿǺʈ

ȸɳ ǺȶǄǵ19ş R ȯȥǺǰʈ ȸɳ ǺȶǄǵ 1 ȸɳ ɉȥǑɳ ǰǺǺɳ ȸɳ Ǭɳ 50 Ž ȟ 0.1 ȁǿǾǺ **:pH Value** ǿǺȽǺǤǿ ǦȶǇę
.10.5ş 8.0 ƙǿ ǿǺȽǺǤǿ ɳŸǤ ÛɉȥǿǍǑǿ ǼǇÊõǺ ɄǝǺǪ ȸɳ ƂǺʅ ǿǺʈ

ǦǺȥǇΣ ǧǿǻǺȒȶŸ ǦǇǄȥȯȥǇşǍǑʈ ǦÊǺǬʈ" ɉȥǺɜ ǨǪǶ ȣȥȍȥɳ ȥȽ Ǻɳ ǼÊǶ ǦÊǺǬʈ ʔǍθ **:Assay** ǦÊǺǬʈ
Bacillus Pumilus ǦǬęǍǿ ǦɳȥȎǶǿ ȳǿǼǺǪèǺ (155 ǦǶǺǬ Û1 ǼŸǬ) "Microbiological assay of antibiotics

Ǧǝǿǟǻ Û8.1-8.0 ƙǞ ǶǝǠŒ ǑǠȽǠǞ ȿǽ Cml ţǿǚ Ǜèȿ ÛǿǠǪǹ ɟǟ Ǘǵ ȸǝǠȮȭ (NCTC 8241 or ATCC 14884)
ǦǲǑȿǻ ǵǼǵȿ 25ȿ 5 ƙǞ ǵǻǠȝ) Ǣè ǠǠǹ ÂǲȭǠǨ ȿǽ ƙÊǲǹȿǛǮǿǓ ȯƺǰȚ Û TS2ȿǓ ÛTS Û8.0 ǑǠȽǠǞ ğǟǽ ǦȶǲȰȝ ğǠÂÊǮ
ǖÛǺŸǑ ǵǼȶǪȞţǟ ǻȿǼΣǟ ǠǮǲƺ ȷƺȮǨ ɟ ȷǓ ǶȽ ǦÊǠǠȰţǟ Ǧȩǻ .°ÿ39-35 ƙǞ ǵǿǟǠǵ ǦǅǿǼǞ ȸȒǶȽȿ Û(Ȱǹ 1 Ȱȭ Ž
ȷƺȮǠ ɟȿ .ǵǿǼȰţǟ ǦǲŸȝǠǠǑǟ ȸǹ %105 ȸǹ ǛǮȭǓ ɟȿ %95 ȸǹ ȰȩǓ estimated potency (*P* = 0.95) ǵǿǼȰţǟ ǦǲŸȝǠǠŸǑ
БǓ ţƺǅǛǑǠǞ Ǧǟƺ ÊȚ ÛǹŸǹ 1 Ȱȭ Ž ǦǲǑȿǻ ǵǼǵȿ 870 ȸǹ ȰȩǓ (*P* = 0.95) ǵǿǼȰţǟ ǦǲŸȝǠǠŸǑ ǖÛǺŸǑ Ƀƺ ŸȞǑǟ ǼȶǪȞţǟ ǼΣǟ
.ǦǲǝǠǹŸǑǟ ǵǻǠţǟ

ERYTHROMYCINI ETHYLSUCCINAS

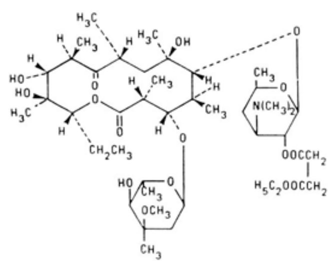
Erythromycin ethylsuccinate ǅǏ ƨ ǏǅŽǆƥƙǏƥǕɛ ǀ ǂǏ ƨ ǀ ƨ üǏƙǏ

for parenteral use Ǐ ǿǆȿΘǁɛ üǂǅŽɏƨǕɛ üШǓ ǅǏ ƨ ǏǅŽǆƥƙǏƥǕɛ ǀ ǂǏ ƨ ǀ ƨ üǏƙǏ

$C_{43}H_{75}NO_{16}$ **:Molecular formula** ǦǲǠǠÂƨǟ Ǧ8ǲÔǑǟ

862.1 **:Relative molecular mass** ǦǲǦÊǠǑǟ ǦǲǠǠÂƨǟ ǦŸǪȮǑǟ

:Graphic formula ǦǲǪǠǲǦţǟ Ǧ8ǲÔǑǟ



:Chemical name ǶǝǠǲȶǲȮǑǟ ǀèɟǟ

Erythromycin 2′-(ethylsuccinate); erythromycin 2′(ethyl butanedioate); [3*R*-(3*R**,4*S**,5*S**,6*R**,7*R**,9*R**,11*R**,12*R**,13*S**,14*R**)]-4-[(2,6-dideoxy-3-*C*-methyl-3-*O*-methyl-α-L-*ribo*-hexopyranosyl)oxy]-14-ethyl-7,12,13-trihydroxy-3,5,7,9,11,13-hexamethyl-6-[[3,4,6-trideoxy-3-(dimethylamino)-β-D-*xylo*-hexopyranosyl]oxy]oxacyclotetradecane-2,10-dione 2′-(ethyl butanedioate); CAS Reg. No. 1264-62-6.

.ǠǦǠǛȭǨ ǦȞǝǟǛǑǟ ǨǼȝ ȿǓ ǦȞǝǟǛǑǟ ǨǼȝ ÜǢǵǠǏ ȐǲǼǓ ȿǓ ȐǲǼǓ ȷƺŸǞ ɃǿƺŸǞ ȧƺȞÊǹ **:Description** Ȥòƺǟ

[illegible] :**Solubility** [illegible] .macrogol 400R [illegible] TS [illegible] 750~)

[illegible] :**Labelling** [illegible]

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

REQUIREMENTS [illegible]

[illegible] 740 [illegible] :**General requirement** [illegible] 1 [illegible]

:**Identity tests** [illegible]

[illegible] A [illegible] B [illegible] C [illegible] D.

[illegible] :A [illegible] (43 [illegible] 1 [illegible]) "Spectrophotometry in the infrared region [illegible] *reference spectrum* [illegible] RS [illegible]

[illegible] :B [illegible] 5 [illegible] 1760~) [illegible] TS [illegible]

[illegible] :C [illegible] 3 [illegible] 2 [illegible] R [illegible] 2 [illegible] 420~) TS [illegible] 2 [illegible] R [illegible]

[illegible] :D [illegible] 5 [illegible] Xanthydrol TS [illegible]

[illegible] :**Sulfated ash** [illegible] 10 [illegible]

[illegible] :**Water** [illegible] Determination of water by "the Karl Fischer method" [illegible] A [illegible] (145 [illegible] 1 [illegible]) [illegible] 0.5 [illegible] 30 [illegible]

[illegible] 50 [illegible] 0.5 [illegible] :**pH Value** [illegible]
.8.5-6.0

[illegible] 100 [illegible] 50 [illegible] :**Assay** [illegible]
[illegible] 1 [illegible]) "Microbiological assay of antibiotics [illegible]" [illegible] (NCTC 8241 or ATCC 14884) *Bacillus Pumilu* [illegible] (155 [illegible] TS2 [illegible] TS1 [illegible] 8.0 [illegible] 8.1-8.0 [illegible] Cml [illegible] .°[illegible] 39-35 [illegible] 1 [illegible] 25 [illegible] 5 [illegible]) [illegible] %95.0 [illegible] estimated potency (P = 0.95) [illegible] 740 [illegible] (P= 0.95) [illegible] %105 [illegible] 1 [illegible].

[illegible]

Additional requirements for Erythromycin ethylsuccinate for Parenteral use

.(56 [illegible] 4 [illegible]) "*Pranenteral Preparations* [illegible]" [illegible]

[illegible]

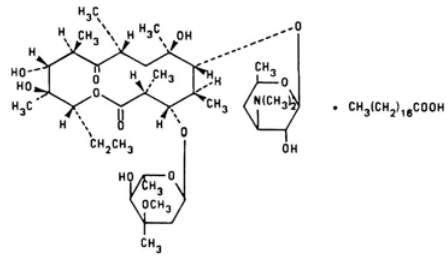
ERYTHROMYCINI STEARAS

stearate Erythromycin [illegible]

$C_{37}H_{67}NO_{13},C_{18}H_{36}O_2$:**Molecular formula** [illegible]

1018 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** ƟəǶƭƐǑǅä ǈèɌä

Erythromycin stearate (salt); erythromycin octadecanoate (salt); [3*R*-(3*R**,4*S**,5*S**,6*R**,7*R**,9*R**,11*R**,12*R**,13*S**,14*R**)]-4-[(2,6-dideoxy-3-*C*-methyl-3-*O*-methyl-α-L-*ribo*-hexopyranosyl)oxy]-14-ethyl-7,12,13-trihydroxy-3,5,7,9,11,13-hexamethyl-6-[[3,4,6-trideoxy-3-(dimethylamino)-β-D-*xylo*-hexopyranosyl]oxy]oxacyclotetradecane-2,10-dione octadecanoate (salt); CAS Reg. No. 643-22-1.

ǛǍǒǗ ɉƺǛǣ ȿǗ ɉƺǛǅä ȐƐǣǗ ȧƺǶÊƞ ȿǗ ÆǵǶì ǛǍǒǗ ɉƺǛǣ ȿǗ ɉƺǛǅä ǦƺǼȝ ǧäǿƺǛǣ :**Description** ƵǒƺǅäǗ .ǼƓǛǍǑǨ ǦǶƏäǛǍǅä ƇǼȝ ȿǗ ǦǶƏäǛǍǅä ƇǼȝ ǗÆǵǶì

R ȳǿƺƺȿǿƺǛǑǅä Ž āȧȿǣ ǗTS (ȯ/ȟ750~) ȯƺǶǯǁqä Ž āȧȿǣ ǗǑǶƫä Ž ǼƐǛƭȝ āȧȿǣ Ƙɗ :**Solubility** ǦƐǶǣȿǾǅä .opalescent ǦƭƐƭɗ ǑƐǶǂä ȻǾȽ ɉƺǑǨ Ǽȩ ǗR Ƙǭɍȧȿ R ȯƺǶǯƐƫȿ

.ǈƐǶǛƨä ǻǶȒƞ ǒȧǻ :**Category** ǦǍǍǅä

.ǒƺȒǅä ȸƞ ǦƐƭƮ ǗȳǶǑǵǣ ǦǑǛ8ƞ ǦǁȿǶǵ Ž ƙÊƐƞȿǛǯǿqä ǧäǿǶƐè ȘǶǵ Ǽƶ :**Storage** ȸǍǍǅä

REQUIREMENTS ƘǦǜƱƘǻ!ƒ

ȸƞ ǦƐǒȿǻ ǵǼǵȿ 550 ȸȝ ǑǍǁ ɍ Ƕƞ ɁǛȝ ƙÊƐƞȿǛǯǿqä ǧäǿǶƐè ɃƺǪƠ :**General requirement** ȳǶǶǅä ǼǛǗǪƫä

ƂǗ ƫƺǛǍǶǣ ǶƭƮƐǪǛȭ ǦǣƺÊƮ $C_{37}H_{67}NO_{13},C_{18}H_{36}O_2$ ȸƞ %77.0 ȸȝ ǑǍǁɍ Ƕƞ ȿǗ ƞǛƞ 1 Ǒȭ Ž ƙÊƐƞȿǛǯǿqä .ǦƐəǶƞǛǅä ǵǻǶƫä

:**Identity tests** ǶǏǊǉǆǈ ǀ ƐƥƑǶǇǆ

• ȸǑƺ ǧäǿǶǪǹɍä ȿǗ ǮǻǍǍƞ A ǿǶǪǹɍä ƺƐǦǗǨ .Dȿ Cȿ B

ǒäǛƭƩä ƘƠ ǦǶìɉä ǦǑǗǶƞ Ž ƟəƺȒǅä ƵƐǗǅä âǶƐȩ" ɉäƺǶȝ ƘƠ 8ƺǒƺƞ ƺȽ Ƕƭȭ ǑǶǍǅä ƺǦǗǁ :A

ƘƠ ǦǶìɉä Ž îǶǑǪƞɍä ƵƐù ƺǣǶǗǪǁ .(43 ǦǶǍǑǅä Ǘ1 ǼǛǑǅ) "Spectrophotometry in the infrared region

ǧäǿǶƐÊǅ *reference spectrum* ƟǶǊǛƫä ƵƐǗǅä Ʉƞ ȿǗ RS ƙÊƐƞȿǛǯǿqä ǧäǿǶƐè ȸƞ ǰǼǍǅä ƵƐǗǅä Ʉƞ ǒäǛƭƩä .ƙÊƐƞȿǛǯǿqä

ɉƺǑ ɉƺǑǪǁ ǗTS (ȯ/ȟ420~) ǑǁǿƺǛȭȿǿǼƐTä Ȑƥ ȸƞ Ǒƞ 2 8ǶȒǁȿ R ɉƺǪèǗ Ǒƞ 2 Ž ƞǛƞ 3 āǿǾǁ :B

ÜᶇȒƸʂ R ÿǿʐʐʂǿʐŸÒöä ȸȵ Ōȵ 2 ȣÅȒ\ .ȸȭäÆöä ɄøǢʐDZǿǧä ÀƥɉäБÜ Ż ȸȵʂ ÀƥɉäБÜ ȯÆGQ\ ɃǾöä ÛБÅŌÒkÀǽ
.ƆäʐDZǿÜ ɈʐŸǽ ÿǿʐʐʂǿʐŸÒöä ČŌGù ǴGÔǩ

.ÀƥÜ ɈʐÖ ɈʐÒQ\ ÜɄǝÅȵ ÿÅƥ Ž ȸǺÊ\ʂ Xanthydrol TS ȸȵ Ōȵ 5 ǿäÆŌȵ ȠŸȵ 5 БÜ ȣÅȒ\ :C

ÜòʐŸǂä ɄŸȣ\ ʡøQǵ ǒÅȵ Ōȵ 10ʂ TS (ȯ/ȟ70~) ȬÍǿʐŸȭʂǿÆETä ȐƥȸȵŌȵ 5 ȝȵ ȟ 0.1 ȤÛŸǽ ȸǺÊ\ :D

ÆEÊȭʂǿÆEȽ ȯʐŸƮ ȸȵ Ōȵ 3 ȝȵ ȸǺÊǩʂ ČEȽÆöä ČŌGÛöä ƫÂøǨ ÛǻƎ\ .ǴÛÊöä ʡŸȝÜ БÜ ČEQ\à Č\ʂÀȭ ǧÅȝÅŌʐ ÆȞÔQǩ

ÜᶇȒƸʂ ȸȁÅÊöä ǒÅƫä ȸȵ Ōȵ 10 ȣÅȒ\ .gel ČȵɎȽ БÜ ȯʐŸǂä ȯʐȞQ\ ÜǻƎQö ȭÀQǩ ÜVS (ȯ/ȯʐȵ 0.1) ÿʐ\ǻʐÔöä

ČǽÅèƀ ɈQǨ ÜTS (ȯ/ȟ55~) ÿʐEÊöÅÒöä ÆÍǿʐŸȭ ȯʐŸƮ ȸȵ Ōȵ 1 ǿäÆŌȵ Ōȵ 1 БÜ ȣÅȒ\ .ȯʐŸǂä (ÆǽÂ\) ɄȡƘʐ

.TS (ȯ/ȟ250~) ȬÍǿʐŸȭʂǿÆETä Ȑƥ Ž Čǽäʂǽ ƘȡÛǧÅGEGǵ ŌÒÎǽ

ȯʐŸǂä ɈÅȭ äǽÜ.R ÿǿʐʐʂǿʐŸȭ Ōȵ 30 ȝȵ ȟ 0.5 ᶇȒƸ :**Erythromycin stearate** ƙÊEȵʂÀǯ\ǿɋä ǧäǿÅEQè

ÛVS (ȯ/ȯʐȵ 0.1) ȬÍǿʐŸȭƘGöä ȐȶɅ ÅÀQÜ ȯÆȞQÊȸ ÛR1 ɄDZŸǯöä ȬEQEèɉä Ȑƥ ȸȵ Ōȵ 50 ȣÅȒ\ ÜȞʐÅȯ

.ÅŌǵɍ ȣʐȍʐȵ ʐȽ ÅȶȭǥÀ\ÅȞƫä ŌȶÒQÊǩʂ

ÜČȍŸȁ Ōȭ ǴȉÀǩ ÜR ÿʐʐʂǿʐŸÒöä ȸȵ Ōȵ 25 ÅƬȵ Ōȭ ƙQEʐÅȓÜ ƙQEȶȭ ȝȵ ᶇȒǺɫ ÛÿʐȶȡÜ äǽ ȯʐŸǂä ɈÅȭ äǽÜ

ʡøQǵ ɄǝÅȵ ÿÅƥ ʡŸȝ washings ǧɍÅÊȸöäʂ filtrate ČǵÅȉÅöä ɈÂȵ ÀǺG\ʂ ÛR ÿǿʐʐʂǿʐŸÒöÅǽ filter ǴȁÀƫä ŌÊȣ\

ÛVS (ȯ/ȯʐȵ 0.1) ȬÍǿʐŸȭƘGöä ȐȶɅ ÅÀQÜ ȯÆȞQÊȸ ÛR1 ɄDZŸǯöä ȬEQEèɉä Ȑƥ ȸȵ Ōȵ 50 ȣÅȒ\ .Ōȵ 30

Ȑƥ ȸȵ Ōȵ 1 Ōȭ .ÆƬƨä âÅEŌȵ Č\ÅƬÅöä ČÛŌǢ ƙEȞǩ ȝȵ ÛVS (ȯ/ȯʐȵ 0.1) ȬÍǿʐŸȭƘGöä ȐȶɅ ÀÅÅȞ\ʂ

ƙÊEȵʂÀǯ\ǿɋä ǧäǿÅEQè ȜʐQƮ ŌŌ\ ɍ Ü$C_{37}H_{67}NO_{13}$,$C_{18}H_{36}O_{2}$ ȸȵ ȠŸȵ 101.8 ǒżÅÒ\ VS (ȯ/ȯʐȵ 0.1) ȬÍǿʐŸȭƘGöä

.ȟ/ȟ 0.770 ȸȝ

Determination of water by ÀÎEʐ ȯǿÅȭ ČŌÀÀÛǽ ǒÅƫä ƙEȞǩ" ɈäʐÀȝ ǨƠ ȣʐȍʐȵ ʐȽ ÅȶȭȸEȞ\ :**Water** ǒÅƫä

ǒÅƫä ȜʐQƮ ÆÂÀ\ ɍ ÜǵǻÅƫä ȸȵ ȟ 0.5 ÿäÆǺQèÅǽ Û(145 ČȞÅÔöä Û1 ÆŸÒä) A ČŌÀÀÛöä Ü"the Karl Fischer method

.ȟ/ȠŸȵ 40 ȸȝ

neutralized ȯÆȞQÊƫä ȯʐǢÅǯ\ɋä ȸȵ Ōȵ 50 Ž ȟ 0.4 ČǽäÀȩ āäǾ\ :**Free stearic acid** ÀΣä ȬÍǿÅEQÊöä Ȑƥ

ÆÊȞɫ .ÆƬƨä âÅEŌȵ ČÅÅƬÅöä ČÛŌǢ ƙEȞǩ ȝȵ ÛVS (ȯ/ȯʐȵ 0.1) ÿʐ\ǻʐÔöä ÆEÊȭʂǿÆEȽ ȯʐŸȞȵ ÀÅÅȞ\ʂ ethanol TS

ȬÍǿʐŸȭƘGöä Ȑƥ ȴDZǵ dzÀÛ\ʂ ǵǻÅƫä ȸȵ ȟ 1 ŌÒö ÿäŸöä VS (ȯ/ȯʐȵ 0.1) ÿʐ\ǻʐÔöä ÆEÊȭʂǿÆEȽ ȯʐŸƮ ȴDZǵ

ȠŸȵ 28.45 ǒżÅÒ\ ȧÀÀöä ȸȵ Ōȵ 1 Ōȭ .ƙÊEȵʂÀǯ\ǿɋä ǧäǿÅEQè ǿÅGQȁä Ž ǵǻÅƫä ȸȵ ȟ 1 ŌÒö ÿäŸöä VS (ȯ/ȯʐȵ 0.1)

.ȟ/ȠŸȵ 185 ȸȝ ÆÂÀ\ ɍ Ü$C_{18}H_{36}O_{2}$ ȸȵ

ȬÍǿʐÅŸÊöä Ȑƥ ȸȵ ČŸEŸȩ ČEȶȭ ȝȵ ƙǨŸǽ ČŌǨʐǽ Ž ȟ 2.0 ŌȞGɫ :**Sodium stearate** ÿʐ\ǻʐÔöä ǧäǿÅEQè

ǵǿäÀǵ ČDZǿÆǽ ÆȵÀɫ ÛTS (ȯ/ȟ1760~) ȬÍǿʐÅŸÊöä ȐȶɅ ČEǢÅǭ ŌȞG\ Ż ÛȤÛŸǽ (ŌȞÎɫ) ÆȵÀɫ ÛTS (ȯ/ȟ1760~)

.ȟ/ŋŸŋ 60 ȸȝ ǼǺÂǨ ɍ Ü$C_{18}H_{35}NaO_2$ ȸŋ ȟ 4.317 ǒżǺȮǺ ǦǺŀȶǰǿ ȸŋ ȟ 1 Ǒõ .ȷǟźǺş ÛǻƎǺ Û°ȳ 800 ǦǟǟÀę

ǰǝǺǪ ȳǼǺǪÊǨ :**Total stearic acid, stearates and water** ǒǺţǟş ǧǟǿǺǪÊǿǟş ǬǺǿǺǪÊǿ Ȑȶ ţźȶf ǧǟǿǺǪèş ƙÊƐŋşÀǯǺǿq ǧǟǿǺǪèş ÀΣǟ ǬǺǿǺǪÊǿ ȐȶΣ ǦǺźǺţǟ ǦǤÊǺǿǟ ǺǶŋ ȝȶƶ ÛǺǺǬǕ ǥǿźǬǾţǟ ǦǶǿȷǟ ǧǺǺǶǪǿǟ ȸȝ ǼǺǺ ɍş %98.0 ȸȝ ɄŸȮǿ ţźȶǑǿ ǑǑǺɍ ÜǒǺţǟ ʔźǪȚş (ǦƐǝǺŋŸǿ ǥǻǺţǟ ƂǕ ţźǄÀǿǺǟ ǦǟźÊȚ ǺȚŸõ) ȳźǺǻźȎǿǟ .%103.0

ǺȶǬ ǦÊǺǺǬţǟ ʔÀθş Ǒŋ 100 ǿǼǬǟ ɭǅǥ ǒǺÛȝq R ȯźǪǺǯţǟ ȸŋ ǦƐźǺǬ ǦƐȶǬ Ž ŋŸŋ 50 ǟǟǾǺ :**Assay** ǦÊǺǺǬţǟ

"Microbiological assay of antibiotics ǦǺźƐΣǟ ǧǟǻǺȐȶŸǿ ǦƐǄźǿźƐşÀȮţǟ ǦÊǺǺǬţǟ" ȷǟźǺȝ ǨƠ 8źòźŋ źȽ ɄǥǴǝǺȮõ (NCTC 8241 or ATCC 14884) *Bacillus Pumilus* ǦŋźȎǶǿǟ ȳǟǼǺǪèǺǟ Û(155 ǦǶǺȎǿǟ Û1ǼŸǑǿ) ȯźŸȚ Û TS2şǕ ÛTS1 Û8.0 ǒǺȽǺǟ ǧǟǿ ǦȶƐǑȝ ǧǺǺÊǷ ǦǝǿǟǻÛ8.1-8.0 ɄǝǺŒ ǒǺȽǺǟ şǿ Cml ţǿǟ Ùèş ÛǿǺǪǹɍǟ

Ǧęǻ .°ȳ 39-35 ǥǿǟÀǥ ǦǄǿǼǟ ȸȐǶǶş Û(Ǒŋ 1 Ǒõ Ž ǦƐǿşǻ ǥǼǥş 25ş 5 ƙǟ ǥǻǺȝ) ǼèǺŋ ǺƐǬÀǪǟ ƙÊƐŋşÀǯǺǿǕ %95 ȸŋ Ǒę Ǖ estimated potency (*P*=0.95) ǥǿǼǬţǟ ǦƐŸȝǺǺŸǿ ǖÛǺŸǿ ǥǼȶǪǶţǟ ǻşǼΣǟ ǺȚƐź ȷźǑǨ ɍ ȷǕ ɄȽ ǦÊǺǺǬţǟ ȸŋ ǑęǕ (*P* = 0.95) ǥǿǼǬţǟ ǦƐŸȝǺǺŸǿ ǖÛǺŸǿ ɃźŸǶǿǟ ǼȶǪǶţǟ ǼΣǟ ȷźǑǺ ɍş .ǥǿǼǬţǟ ǦƐŸȝǺǺǿǟ ȸŋ %105 ȸŋ ÀǯǬǕ ɍş .ǦƐǝǺŋŸǿǟ ǥǻǺţǟ ƂǕ ţźǄÀǿǺǟ ǦǟźÊȚ ÛŋŸŋ 1 Ǒõ Ž ƙÊƐŋşÀǯǺǿq ȸŋ ǦƐǿşǻ ǥǼǥş 550

ØØØØØ

ETHER ANAESTHESICUS

Anaesthetic Ether ȸǿǪǶǺǄǺƐ ȸǨƙÛƐ

$C_4H_{10}O$:**Molecular formula** ǦƐǺǺÂƨǟ Ǧ8ƐȎǿǟ

74.12 :**Relative molecular mass** ǦƐǤÊǺǿǟ ǦƐǺǺÂƨǟ ǦŸǪȮǿǟ

:**Graphic formula** ǦǪǺƐǤţǟ Ǧ8ƐȎǿǟ

$C_2H_5—O—C_2H_5$

:**Chemical name** ɄǝǺƐȶƐȮǿǟ ɭèɍǟ

Ethyl ether; 1,1′-oxybis[ethane]; diethyl ether; CAS Reg. No. 60-29-7.

.ǥÂǶȶŋ ǦǶǝǟǿ şǿ ÜǺǺÛǪŋ ÛȷźŸǿǟ ƇǼȝ ÛŽǺò ÛǦǬÀΣǟ ǼǺǼì ǑǝǺè :**Description** Ƶòźǿǟ

.R ȳǿźźşǿźŸȮǿǟş TS (ȯ/ȟ750~) ȯźǪǺǯǺqǟ ȝŋ ǯşÂŋ ÜǒǺţǟ ȸŋ ǒǟÂǄǕ 10 ȝŋ ǯşÂŋ :**Miscibility** ǦƐǄşÂţǟ

.ȳǺȝ ǿǼǻŋ :**Category** ǦǺǺǿǟ

ǦDZǿǼǟ ÛŏζȒŏǟ ȸƞ ǦĿȶƮ ÛȸƞǗ ŌȮÎǟ ǦŌŸ8ƞ ǦζȦDZ ǦĂşȦǵ Ž ǿǼǺţǟ ƘǪɉǟ ȷÂƩ ȷǗ Ǣƶ :**Storage** ȸĂÂǺǪŏǟ
.ƞŸõ 1 ȸʒ ǼĂÂǨɍ ǦĿȶȮǟş Û°ÿ 15 ȸʒ ǼĂÂǨɍ ǥǿǟȦǵ

Highly ǥǼÎǟ ǟȦȤǪŏŸŏ ŌǟȦę" ǦŸƤ ʔŸʒ ǿǼǺţǟ ƘǪɉǟ ǦĂşȦǵ Ž ǦĿȶÊǪŏǟ ȌȦǨ ȷǗ Ǣƶ :**Labelling** ȽǼèζǪŏǟ
ȷǗ Ǣƶş .ǼȦȞǪǐǟ ǢǦÊǨ ȷǗ ȸȮƩ ɄǿǪŏǟ ǥǿǟȦȞŸŏ ǿǼÔƞ ɃǗ şǗ ȡzζǪȦƞ ǢƮ ɃǗ ǟȦŌǟ ÿǼǺǪÊĂɍ ."flammable
.ȣȦȒƫ antioxidant ǼÊõǟǨ ǻȦȒƞ ɃǗ ǦĿȶõş ȽèǟȦõǾĂ

Ǣƶş .ǢèȦĂƞ ǼÊõǟǨ ǻȦȒƫ ʔŸʒ ǿǼǺţǟ ƘǪɉǟ ɃzǪƷ ȷǗ ȸȮƩ :**Additional information** ǦĿζȦȓǗ ǧȦƞζŸȞƞ
Ž ɄŌǪǪţǟ ƘǪɉǟ ȷǗ ǟǼǗ .Ǧʒȁè 24 ȸƞ ȯζüǗ ǥǼƞ ǦĿŸȍɉǟ ȼǪĂşȦǵ ȸƞ ţÂȦ Ǽę ȷȦõ Ȧƞ ǟǼǗ ȦĂǼǺǪŸŏ ŌȶȞǪÊĂɍ ȷǗ
ǼĿÊõǗ şǗ ƙDZÊõǟɉ şǗ ŏǟζȽǟ ʒƞ ǦDZşÂȶţǟ ƘǪɉǟ ǥȦȤǗ ǼȞǨɍ :ȦĂǾƠ .ǦʒȦÊǟ ǿζȽǼǪĂ Ǽę ǼĿǟÂDZ ǦŸȶȞǪÊţǟ ǧȦĂşȦȈǟ
ɃǗ Ž ȡzζǪȦƞ ǢƮ ɃǗ ŌȶȞǪÊĂɍ .explosive ǥȦDZȦǪƞ concentrations ȦĿõǟȦǪŏǟ ȒǞǟ ǼĂʒ nitrous oxide ȁşȦǪǾŏǟ
.ǿȦǪȿɍǟ ŏǟȦDZǗ ŏȦǪǗ ǧȦęşɉǟ ȸƞ Ǩęş

REQUIREMENTS ƘǦȶǪƱǾǼǖ!ƒ

:**Distillation range** ƘÛŌǪŏǟ ȯȦƒ
• ȼǪǗ ȸƫ ǥǿζÛȽǟ ȦȶŌǗ ȷǗ ȷǗ ȸǨǗ ƘÛŌǪŏǟ ȯȦƒ ŌǟȦÊǟ ǿȦǪȿɍǟ ȝǗ ǟǼǗ ǢǼDZǪÊĂ ɃǗ ǿȦǪȿǟ ƘǦŏǟ ǧǟǼǼÊõşƘǦŏǟ
.Peroxides

ȧζζ ƘÛŌǪŏǟ ǦŸDZζǵ ƘǺÊǨ Ž ɌǟȦζɋǟ ǢǼDZǪŏ ǦƞǟƔŏǟ ǧȦüȦǪǵɍǟ ǿȦůǨş ÛǦèȦĂƞ ƘǺÊǨ ǥǼǼȤDZ ÿǼǺǪÊǨ
.°ÿ 35.0ş 34.0 ƘǟŌƞȦȮǟǟ ǾÛŌǪĂ ȝǗ Ütest liquid ǿȦǪȿɍǟ ŌǟȦè ɁζǪÊƞ

. $d_{20}^{20} = 0.713 - 0.716$:**Relative density** ǦǼǦÊǟǟ ǦζȦǩȮǟ

:**Non-volatile residue** ǥǿǼÛǟ Ƙȡ ǦŏȦȶǧǟ
• ȼǪǗ ȸƫ ǥǿζÛȽǟ ȦȶŌǗ ȷǗ ȸǨǗ ǥǿǼÛǟ Ƙȡ ǦŏȦȶǧǟ ŌǟȦÊǟ ǿȦǪȿɍǟ ȝǗ ǟǼǗ ǢǼDZǪÊĂ ɃǗ ǿȦǪȿǟ ƘǦŏǟ ǧǟǼǼÊõşƘǦŏǟ
.Peroxides

.Ōƞ/ÿǟȦȡşȦȮƞ 20 ȸƞ ȦǩõǗ ʔŌǪǪɍ ÜȷȁζȽş Ǧʒȁè 1 ǥǼƞ °ÿ 105 ǦDZǿǼǺǟǟ ǦŏȦȶǧǟ ȤȦƟ ÛȦÂǪǨ ɄȮŏ Ōƞ 5 õȦǪȽ

ǦǼDZȦDZǟ ǥȁǟǼè ǧǟǼ Ōƞ 50 ȽDZɊ ǦŸDZζǵ Ž TS (ȯ/ȟ750~) ȯζǪǩǟǪǟ ȸƞ Ōƞ 10 ʒȓζĂ :**Acidity** ǦȓζȶƩǟ
ǼǼÊõşǿǼǼȽ ȯζŸƮ ȸƞ ǦǼζȦõ ǦĿȶõş TS ȯζǪǩǟǗ/ƘǟǟǩζȦ ȯζǟǾζ ȯζŸƮ ȸƞ Ōƞ 0.5 ȣȦȒĂş Üglass- stoppered flask
ÜǦǼǪǟǪ 30 ǥǼƞ ǰĂÂţǟ ȒǞ ǼȞǟ ÿşǼĂ ɄŸȦǪǟǨ ȷζŸǟ ȷζŏ ȸǟÛʒǪ ǧǪζǟȦȮŏǟ ȸƞ ǺȦȞǟ VS (ȯ/ȯζƞ 0.02) ÿζĂǥζÔŏǟ
VS (ȯ/ȯζƞ 0.02) ÿζĂǥζÔŏǟ ǼǼÊõşǿǼǼȽ ȯζŸƮ ȸƞ ȣȦȒĂş ÛȤÛŸǟ ǯÂƩ ÛǿȦǪȿɍǟ ŌǟȦè ȸƞ Ōƞ 25 ȣȦȒĂ
0.4 ȸƞ ȦǩõǗ ǦζȦȓǗ Ȧƞɉǟ ǢŸÛǪĂɍ ÜǦǼǪǟǪ 30 ǥǼƞ ǰĂÂţǟ ȒǞ ǼȞǟ ɄŸȦǪǟȠǟ ȷζŸǟ ÿşǼĂ ʔǿǪǵ ǧǪζǟȦȮŏǟ ȸƞ ǺȦȞǟ

[illegible].

[illegible] **Peroxides**: [illegible] 10 [illegible] 2.0 [illegible]

[illegible] 1.0 [illegible] refernce solution [illegible] TS. [illegible]

[illegible] TS (60~) [illegible] 100 [illegible] 0.10 [illegible] 2.0 [illegible]

[illegible] TS. [illegible]

[illegible] "Colour of liquids" [illegible] (53 [illegible]).

[illegible] **Aceton and aldehydes**: [illegible] 2 [illegible] alkalin potassio-mercuric iodide

TS [illegible] 12 [illegible] 1.5 [illegible] 10 [illegible].

[illegible] 10 [illegible] 5 [illegible]

[illegible] 40 [illegible]

5 [illegible] distillate.

[illegible] **Foreign odour**: [illegible] 10 [illegible]

[illegible].

ØØØØØ

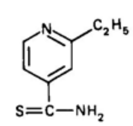
ETHIONAMIDIUM

Ethionamid [illegible]

[illegible] **Molecular formula**: $C_8H_{10}N_2S$

[illegible] **Relative molecular mass**: 166.2

[illegible] **Graphic formula**:



[illegible] **Chemical name**:

2-Ethylthioisonicotinamide; 2-ethyl-4-pyridinecarbothioamide; CAS Reg. No. 536-33-4.

[illegible] **Description**: [illegible].

ȯζφǺǯɋ Ž ȷǺǣşǾȫ ǾƐŸȩ ÜR ȯζφǺǯƐƫ Ž ā şǽ ÜǑǺƫ Ž ǺƐŸɫȝ ā şǽ Ƙɖ :**Solubility** ǦƐφǺǣşǾȫ
.Ƙǭɼş R ȳǿζζşǿζŸǑȫ Ž ȷǺǣşǾȫ ǴƐƕ ɨ ÜTS (ȯ/ȟ750~)

.Antileprosy ȳǾDzŸ ǻǺȒɳ ǒşǻ :**Category** ǤǺǺȫ

.ǻǿǺ ȷǺǑɳ Ž ǦφǺƯ ÛǒζȒȫ ȸɳ ǦƐɫƬ ÛȳǺǑǵǖ ǦǾŸȣɳ ǤşǺǵ Ž ǼƐɳǺφζƐǭɋ ȘǺǵ Ǣƶ :**Storage** ȸǺǺǺǭȫ

.ǒζȒŸ ô ǺȞǭȫ Ǽȝ ǺǑǻ ǼƐɳǺφζƐǭɋ ȷζ ǴǤǑ :**Additional information** ǦƐζǺȓ ǧǺɳζŸȞɳ

REQUIREMENTS ƘǤǘƱǨǅ!ƒ

ȸɳ %101.0 ȸȝ ǼǺǺ ɼş %98.0 ȸȝ ǑǺ ɼ Ǻɳ ɁŸȝ ǼƐɳǺφζƐǭɋ ɃζǬƷ :**General requirement** ȳǺȞȫ ǢŸÛǭƫ
.ǤǺǺǑȫ ǥǻǺƫ Ƃ ƫζǅǺǺ ǦζȆƬ Û$C_8H_{10}N_2S$

:**Identity tests** ƕǏǋǊǁɛ l ɛƥƑǴƢɛ

- .Dş Cş B ǧǿǺǭȵɼ ş ǺȞɳ Dş A ȸǿǺǭȵɼ ȨƐǤÛ ȸǑζ

ǒǺɫƩ ƘƠ ǦȞɨȷ ǤǑÛǺɳ Ž ɄɘζȒȫ ƵƐÛȫ âǺƐȩ" ȷζǺȝ ƘƠ Ȣζǒζɳ ζƚ ǺɫǬ ǸƕǺȫ ȨǤÛ :A
ȝɳ ǒǺɫƩ ƘƠ ǦȞɨȷ Ž ƵƐÛȫ ȨǺǺÛǭ .(43 ǦƕǺǑȫ Û1 ǼŸǑ) "Spectrophotometry in the infrared region
.ǼƐɳǺφζƐǭȒ *reference spectrum* ɄȞǅǺƫ ƵƐÛȫ ȝɳ ş RS ǼƐɳǺφζƐǭɋ ȸɳ ǰǺǺȫ ƵƐÛȫ

Ƃ ǰǺƫ ǿƚ ȸɳ ɳŸ 10 ǑǺ Ż Û2,4-dinitro chlorobenzene R ǥǺɳ ȸɳ ȟ 0.10 ȝɳ ȟ 0.05 ǯǺɛ :B
ǰǭǺ ÜTS1 ȯζφǺǯǺ/ȳζƐȅǺζǤȫ ǼƐȆǬşǿǼƐ ȯζŸƬ ȸɳ Ǒɳ 3 ȢǺȒş ǻƎ .ǿǺƮǑφɼ ɁǿǭǴ ȸǺȆş ǿǺǭȵ ā ζǤ
.ƂǺǑǺǺ – Ǻƥ Ƃ Ǻƥ ȷζ

ǧǺƐȅ ȧǿş ǰǺǺȫ ǿǺǺǤȫ ȷƺŸ ÜVS (ȯ/ȯζɳ1) ǬǺǿζŸǬşǿǼƐȫ Ȑƥ ȸɳ Ǒɳ 5 ȝɳ ȟ 0.1 ȸǺȆǺ :C
.ǻζȅȷǺ R ȋ ǺǒǺȫ

.°ȳ 162 ǤǺǺȩ ÛǿǺƮǑφɋ ǥǿǺǵ ǤǅǿǺ :D

ƘƠ Ȣζǒζɳ ζƚ ǺɫǬ ǿǺǭȵɼ ȯζŸƬ ƘȒƠ ǑǅȷƐ ȟ1.0 ȳǼǺǭȆǺ :**Heavy metals** ǦŸƐǑǯȫ (ǧǺǺŸǺȫ) ȷǻǺȞƫ
ǦƕǺǑȫ Û1 ǼŸǑ) 3 ǒǺǅɋ ǢȆɯ Û"Limit test for heavy metals ǦŸƐǑǯȫ (ǧǺǺŸǺȫ) ȷǻǺȞƫ ǑǅȷƐ ǿǺǭȵɼ" ȷζǺȝ
.ȟ/ȳǺɖşǺǑɳ 20 ȸȝ ǼǺǺ ɼ Ü(128 ǦƕǺǑȫ Û1 ǼŸǑ) A ǤǺǺÛȫ ǢȆɯ ǦŸƐǑǯȫ ȷǻǺȞƫ ɁζǭƬ ƙȞǺ Ü(127

.ȟ/ɳŸɳ 1.0 ȸȝ ǼǺǺ ɼ :**Sulfated ash** ƘǺŸȆƫ ǻǺɳǺȫ

ȸɳ ǺǯǬ Ǽ ǑǺ ɼ Ü°ȳ 105 ǥǿǺǵ ǤǅǿǼǺ ƘǺǺǯȫ ȷǺζȫ ɁǿǭǴ ƵǺƶ :**Loss on drying** ƵƐǺǅǭǺ ǼǑǺȫ
.ȟ/ɳŸɳ5.0

[illegible] **Related substances** [illegible] R4 [illegible] (84 [illegible] 1 [illegible]) "Thin-layer chromatography [illegible] 10 [illegible] R [illegible] 1 R [illegible] 9 [illegible] 0.10 [illegible] (B) [illegible] 1 [illegible] 20 [illegible] (A) [illegible] R [illegible] 1 [illegible] 0.04 [illegible] (C) [illegible] 1 [illegible] 254) [illegible] .B [illegible] A [illegible] .C [illegible]

[illegible] R1 [illegible] 50 [illegible] 0.15 [illegible] **Assay** [illegible] Non-aqueous [illegible] VS (0.1 [illegible]) [illegible] VS (0.1 [illegible]) [illegible] 1 [illegible] (142 [illegible] 1 [illegible]) A [illegible] "titration [illegible] 16.62 [illegible] $C_8H_{10}N_2S$.

ØØØØØ

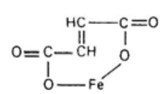
FERROSI FUMARAS

Ferrous fumarate [illegible]

$C_4H_2FeO_4$ **:Molecular formula** [illegible]

169.9 **:Relative molecular mass** [illegible]

:Graphic formula [illegible]



:Chemical name [illegible]

Iron(2+) fumarate (1:1); iron(2+) (*E*)-2-butenedioate (1:1);
CAS Reg. No. 141-01-5.

[illegible] **:Description** [illegible]

.TS (750~ [illegible]) [illegible] **:Solubility** [illegible]

.Iron supplement [illegible] **:Category** [illegible]

Storage :

REQUIREMENTS

General requirement : %93.0 ... %101.0 ... $C_4H_2FeO_4$

Identity tests :

A: 0.4 ... 10 ... (1 ...) VS ... 1.0 ... (B ... VS (...1) ... 15 ... TS ... 0.2 ... VS (... 1) ... 2.0 ... 2.0 ... TS (...45) (II) ...

B: ... A ... C ... General "identification tests (121 ...)

C: 0.5 ... 1 ... R ... 0.5 ... 0.15 ... TS (...1760~) ... fluorescence.

Heavy metals : 1.0 ... 5 ... TS (...420~) ... 15 ... TS (...420~) ... 4 ... TS (...1000~) ... 6 ... 1 ... R ... 20 ... 20 ... (...100~) ... pbR ... 1 ... 1 ... pbTS ... 40 ... pbTS ... 1 ... pbTS Limit test ... "for heavy metals ... A (128 ...) ... 100 ...

Arsenic : 0.2 ... 1.5 ... R ... 10 ... AsTS ... 20 ...

ǦŸǅ:ǵ Ƃǚ ŌŌȀ .ŏǻ Ōŋ 10ş brominated hydrochloric acid AsTS ÿşƎ¤ ¢Ǝǚ 8ȦȒţ ŌÆǯŸŌşøǼǑŢ Ȑ þ ŌòƷȀ ǕȀȀòɉ ɉǮŸ ţȂøȂ stannous chloride AsTS ɃȀǼÔŌǾ ǼǾǯŸŌ ȸŋ ǦƷȦŌ ǦƗȶŌ 8ȦȒȀş Ûǥǩ8ò ŌǅƗɉ ɃǼΣ øȦǗnɍ" ɉȁǯȀɜ ǨƠ 8ƷòƷŋ ƷȽ Ȧŋ ÆÊШ ǥøȦÛŌȦ ŌȶȞ ŌȶȮǪÊȀ ǕŌŋ 22 ȀÛŌȀş ǮǒŌţ .ȟ/ÿȀȁđşȀÒŋ 5 ȸɜ ǸƗøÂ ʔƷǪŢ ǼȀȀ ɍ Û(130 ǦȞȦÔ Û1 ǼŸŎ) "Limit test for arsenic ǸƗøÂ

Ȑ þ ȸŋ Ōŋ 10ş ŏȦŋ Ōŋ 100 ȸŋ ǰȀȂŋ Ž ÛǦùƷǦȒŋ ǦȹşàƷŋ Ûȟ3 Ǧȁȁę ā ȀǾȀ :**Ferric iron** ŌȀǼȀǼΣ ǼȀǼǵ ÿƷƗèȦǩƷǦ ǼȀǻƷȀ ȸŋ ȟ 3 8ȦȒȀş Ǧ3ȀÊ ǻƎȀ .ɉȦşǾ ʔøǪǵ ɉǼŸ8Ȧ ƙȂÊǪȦ TS (ȯ/ȟ420~) ŌȀǯƷŸŌşøǼƗŢ ğȦȀŸèƷǪ ȯƷŸȞŋ øȀȞǪţ ǻƷƗ ȀȀȞȀ .ǦŌƗęǻ 15 ǥǼŋ ÿŸŢ Ž øȀŌǪèŸ ŌȀǩ ÛȀşǼǪȦ ʓȂƺş ǦŸǅƷΣ ĘŸ8ǩ ÛR ǥǻȦţ ɉşǻ ǦƗŸȶȞ ǻȦȞǩ .ǥȀȀȞţ ǦȀŒ ǼȀɜ 8ȦȒȀ ɃǾ ÛȀȞÎȶŌ TS ȦÎȀ ÿȀǼÁǪèȦ ÛVS (ȯ/ȯƷŋ0.1) ÿƷȀǻƷÔ ȯƷŸȚ ȸŋ Ōŋ 1 ŌŌ .ǥȀȀȞȶŸ ǦŋàŸ VS (ȯ/ȯƷŋ 0.1) ÿƷȀǻƷÔ ğȦȀŸèƷƗ ĻǅƷΣȦ ȧȀȀ ȸƗȞȀş ǦòƷȞȦţ ȸɜ ŌȀǼȀǼΣ ǼȀǼǵ ʔƷǪŢ ǼȀȀ ɍ ǕŌȀǼȀǼΣ ǼȀǼǵ ȸŋ ŋŸŋ 5.585 ŏżȦÒȀ VS (ȯ/ȯƷŋ 0.1) ÿƷȀǻƷÔ ğȦȀŸèƷǪ .ȟ/ŋŸŋ 20

Ž ǻƎȀ ÛŏȦŋ Ōŋ 20ş TS (ȯ/ȟ70~) ŌȀǯƷŸŌşøǼƗŢ Ȑ þ ȸŋ Ōŋ 8 ɜŋ ȟ0.15 ʔŸ8Ȁ :**Sulfates** ğȦȀŸÊ Limit test ğȦȀŸÊ ŌǅƗɉ ɃǼΣ øȦǗnɍ" ɉȁǯȀɜ ǨƠ 8ƷòƷŋ ƷȽ ȦȶŌ ǦǥȦȉȀ ɜŋ ŌȶȞ ŌȶȮǪÊƗ ǕǦȉȀş ǰŸ .ȟ/ŋŸŋ 2 ȸɜ ğȦȀŸÊ ʔƷǪŢ ǼȀȀ ɍ Û(125 ǦȞȦÔ Û1 ǼŸŎ) "for sulfates

10 ȸŋ ȀʒŌǚ ǼŌȦȀ ɍ Û°ÿ 105 ǥøȀǵ ǦǅøǼ ǨȁȦʒ ɉàƷ ʔøǪǵ ƷȦƶ :**Loss on drying** ƷƗȀǅƷǪȦ ǼŌȦ .ȟ/ŋŸŋ

ɜŋ TS (ȯ/ȟ100~) ŌȀǯƷȦŸÊ Ȑ þ ȸŋ Ōŋ 7.5 Ž ÛǦùƷǦȒŋ ǦȹşàƷŋ Ûȟ0.3 Ǧȁȁę ā ȀǾȀ :**Assay** ǦÊȀȦŌţ ceric ammonium ŌȀǨè ÿƷƗƷŋǚ ğȦȀŸè ȯƷŸȞŋ ǥȀȉȀǥŋ ȀȀȞȀş ÛŏȦŋ Ōŋ 25 8ȦȒȀş ÛǻƎȀ ÛƷÛŸ ƙȂÊǪ ğȦȀŸè ȯƷŸȚ ȸŋ Ōŋ 1 ŌŌ .ȀȞÎȶŌ TS ƙȯşȀʒǪȀƗƷƷǪøşǚ ȯƷŸȚ ȸŋ Ōŋ 0.1 ÿȀǼÁǪèȦ ÛVS (ȯ/ȯƷŋ 0.1) sulfate ŌȀǨè ÿƷƗƷŋǚ ȸŋ ŋŸŋ 16.99 ŏżȦÒȀ VS (ȯ/ȯƷŋ 0.1) ŌȀǨè ÿƷƗƷŋǚ .$C_4H_2FeO_4$

øøøøø

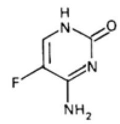
FLUCYTOSINUM

Flucytosine ǄȋȒǋƗȋƨǋƚƺ

$C_4H_4FN_3O$:**Molecular formula** ǦƗȦȀÂƨ Ǧ8ƗÔ

129.1 :**Relative molecular mass** ǦƗǦÊȀ ǦƗȦȀÂƨ ǦŸǪÒ

:**Graphic formula** ǦƗȹȦƗǦţ Ǧ8ƗÔ



:**Chemical name**

5-Fluorocytosine; 4-amino-5-2(1-*H*)-pyrimidinone; CAS. Reg.No. 2022-85-7

:**Description**

:**Solubility** (~750) ... R ... R.

:**Category** Antifungal.

:**Storage**

:**Additional information** 295 °.

REQUIREMENTS

:**General requirement** %98.5 ... %101.0 ... $C_4H_4FN_3O$.

:**Identity tests**

- A ... C ... B ... D.

:A ... "Spectrophotometry in the infrared region" (43 ... 1) ... RS ... *reference spectrum*.

:B ... 5.0 ... (0.1 ...) VS ... 230 ... 350 ... 286 ... 1 ... 0.36.

:C ... "Fluorouracil" ... A ... B.

:D ... 0.05 ... 5 ... 0.15 ... TS1 ...

:**Heavy metals** 1.0 ...

[illegible] (125 [illegible] 1 [illegible]) "Limit test for heavy metals [illegible] 20 [illegible] (128 [illegible] 1 [illegible]) A [illegible].

Sulfated ash: [illegible] 1 [illegible].

Loss on drying: [illegible] 105 [illegible] 15 [illegible].

Fluorouracil: [illegible] Thin-layer chromatography" (84 [illegible] 1 [illegible]) R6 [illegible] 70 [illegible] 20 [illegible] R [illegible] (~750 [illegible]) [illegible] 1 [illegible] TS (10 [illegible]) [illegible] 10 TS [illegible] 10 (A): [illegible] R [illegible] 15 [illegible] 1 [illegible] RS [illegible] 10 (B): [illegible] 1 [illegible] 20 (C): [illegible] 10 [illegible] 1 [illegible] RS [illegible] 20 (D): [illegible] 1 [illegible] unsaturated [illegible] (254 [illegible]) [illegible] D [illegible] C [illegible].

Assay: [illegible] 0.3 [illegible] 50 [illegible] R [illegible] R1 [illegible] 100 [illegible] (0.1 [illegible]) [illegible] Non-aqueous [illegible] VS [illegible] (0.1 [illegible]) VS [illegible] titration" (142 [illegible] 1 [illegible]) A [illegible] 1 [illegible] 12.91 [illegible] $C_4H_4FN_3O$.

[illegible]

Additional requirement for Flucytosine for parenteral use

[illegible] "*parenteral preparation* [illegible] (56 [illegible] 4 [illegible]).

[illegible]

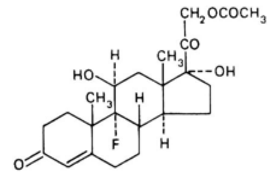
FLUDROCORTISONI ACETAS

Fludrocortisone acetate ǅǎǊƦǐƗƥǊǀǊǏǂǋǂ ǀ ǅƗǐ ƨ ƈ

$C_{33}H_{31}FO_6$ **:Molecular formula** ǦƸǵǖƨ ǦȢƸÔǖ

422.5 **:Relative molecular mass** ǦƸÊǖ ǦƸǵǖƨ ǦƳÒǖ

:Graphic formula ǦƸǵƸţ ǦȢƸÔǖ



:Chemical name ȾǝƸŧƸÒǖ ǈèɍ

9-Fluoro-11β,17,21-trihydroxypregn-4-ene-3,20-dione 21-acetate; 21-(acetyloxy)-9-fluoro-11β,17-dihydroxypregn-4-ene-3,20-dione; CAS Reg. No. 514-36-3.

.ǛƸǀǖÕǩ ǦȞǝǖǖ ƇƸȝ ȿǓ ǦȞǝǖǖ ƇƸȝ ǕƸǀǖÕǩ ȒƸǓ ȿǓ ȒƸǓ ȷǶǜ ɃǿǶǜ ȧǶȞÊȠ **:Description** ǵòǶǖ

ǕR ȳǿǶǶȿǿǶǜÒǖȿ TS (ȯ/ȟ750~) ȯǶǀǵǖǭǖ Ž ȷǵȿǾǖ ÕƸǜ ǕòǵŢǖ Ž ǛƸǜŧȝ ǡǖȿǣ Ƙ **:Solubility** ǦƸǵȿǾǖ

.R Ƙǭȷǖ Ž ȷǵȿǾǖ ǴƸȞȉ

.Adrenal hormone ɃǖǐŎ ȷǶȠǖȽ **:Category** ǦǖǖǖǷ

.ǛǶȒǖ ȸȠ ǦƸŧƮ ǕǜǴƸƵ ǦÕǩȢȠ ǦǖȿǵǴ Ž ȷȿǖƸǩǿǶÕȿǿǵǶǜǖǖ ǧǖǭƸèǓ ȘǖǴ ǢƵ **:Storage** ȸǖǖǖǭǖ

.hygroscopic ǦǜüǖǭÊȠ ǵǖȠ ȷȿǖƸǩǿǶÕȿǿǵǶǜǖǖ ǧǖǭƸèǓ ǵǖȠ ǢǩƸ **:Additional information** ǦƸǶǖȓǓ ǧǖȠǶǜȠ

REQUIREMENTS ƘǦƸǜƱǓǕƸǕ!ƒ

Ǣǵǖǖǖɍȿǖǖǖǖǖǖǖǖǖǖǖǖǖǖǖǖǖ %96.0 ȸȝ ÕǖǖɍǖȠ ȝǜȝ ȷȿǖƸǩǿǶÕȿǿǵǶǜǖǖ ǧǖǭƸèǓ ɃǶǭƠ **:General requirement** ȳǖǩǖ ǢǜǕǭţǖ

.ǦǖǖÒǖ ǵǖţǖ ɃǓ ţǶǅǖǖǖǖ ǦǶǶÊƮ Ǖ$C_{33}H_{31}FO_6$ ȸȠ %104.0 ȸȝ

:Identity tests ȟǐǊǊǋǂ ǀ ǂƥǅǦǂǋǂ

• ȸǖǶ A ǿǖǭȠɍǖ ǖǖǖǖ ǖǖǖ ȸǖǿǖǭȠɍǖ ȿǓ ǖǖǖǖǖǖǖǖǖ B ȿǓ ǖǖǖǖǖ Ǹ ǖǖǖ .CȿB

A: ǖǖǖǖ Ǖǖǖǖǖǖǖǖǖǖǖǖǖǖǖǖǖǖǖǖǖǖǖǖǖǖǖǖ ǖǖǖǖǖǖǖ Ž ǖǖǖǖǖǖǖ ǖǖǖ ǖǖǖǖ Ƙ Ơ ǖǖǖǖǖǖ "Spectrophotometry in the infrared region" (ǢǜÕǖ 1Ǖ ǦȞÒǖ 43). ǖǖǖǖǖ ǵǖü ǖǖǖǖǖǖ Ž ǖǖǖǖ Ơ

[illegible] *reference spectrum* [illegible] RS [illegible] .

"Thin-layer chromatography [illegible] :B [illegible] 10 [illegible] R1 [illegible] (84 [illegible]) [illegible] 5 [illegible] 90 R [illegible] 16 [illegible] 2 [illegible] R [illegible] 25 R [illegible] 75 [illegible] R [illegible] 1 R [illegible] 9 [illegible] 2 [illegible] 2.5 [illegible] :(B) [illegible] 1 [illegible] 2.5 [illegible] :(A) [illegible] 15 [illegible] 1 [illegible] RS [illegible] 15 [illegible] °[illegible] 120 [illegible] 10 [illegible] °[illegible] 120 [illegible] TS [illegible] (365 [illegible]) [illegible] B [illegible] A [illegible] .

[illegible] 5 [illegible] 0.5 [illegible] :C [illegible] 3 [illegible] 5 [illegible] .

[illegible] 10 [illegible] :**Specific optical rotation** [illegible] . $[\alpha]_D^{20°C} = +148 \text{ to } +156°$ [illegible]

[illegible] 1.0 [illegible] :**Sulfated ash** [illegible]

[illegible] 105 [illegible] :**Loss on drying** [illegible] 10.

[illegible] 1 [illegible] :**Ultraviolet absorption** [illegible] .0.42-0.39 [illegible] 240 [illegible] (dehydrated) R [illegible] 10 [illegible]

"Thin-layer chromatography [illegible] :**Related substances** [illegible] Silicagel R2 [illegible] (84 [illegible] 1 [illegible])

[illegible] 0.2 [illegible] 5 [illegible] 95 [illegible] 1 [illegible] 9 [illegible] 1 [illegible] 0.30 [illegible] :(B) [illegible] 1 [illegible] 15 [illegible] :(A) [illegible] 1 [illegible] 10 [illegible] 105 [illegible] 254) [illegible] .B [illegible]

Assay [illegible]:

- [illegible]

[illegible] TS (750~) [illegible] 25 [illegible] TS (750~) [illegible] 10 [illegible] 250 [illegible] 2.0 [illegible] 25 [illegible] 10.0 [illegible] 50 [illegible] R [illegible] TS [illegible] 2.0 [illegible] 1 [illegible] R [illegible] 25 [illegible] TS (750~) [illegible] 30 [illegible] 525 [illegible] 1 [illegible] $C_{23}H_{31}FO_6$ [illegible] TS (750~) [illegible] 10 [illegible] RS [illegible]

ØØØØØ

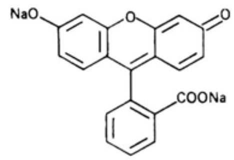
FLUORESCEIN NATRICUM

Fluorescein sodium [illegible]

$C_{20}H_{10}Na_2O_5$ **:Molecular formula** [illegible]

376.3 **:Relative molecular mass** [illegible]

[illegible] **Graphic formula**:



[illegible] **Chemical name**:

Fluorescein disodium salt; 2-(6-hydroxy-3-oxo-3*H*-xanthen-9-yl)benzoic acid disodium salt; 3′,6′-dihydroxyspiro[isobenzofuran-1(3*H*),9′-[9*H*]xanthene]-3-one disodium salt; CAS Reg. No. 518-47-8.

[illegible] **Description**: [illegible]

[illegible] **Solubility**: [illegible] 1.5 [illegible] (~750 [illegible]) TS [illegible]

[illegible] **Category**: [illegible]

[illegible] **Storage**: [illegible]

[illegible] **Additional information**: [illegible] hygroscopic.

REQUIREMENTS [illegible]

[illegible] **General requirement**: [illegible] 98.0% [illegible] 100.5% [illegible] $C_{20}H_{10}Na_2O_5$ [illegible]

[illegible] **Identity tests**:

A: [illegible]

B: [illegible] (20 [illegible]) [illegible] (~60 [illegible]) TS. [illegible] "General identification tests" [illegible] B [illegible] (123 [illegible] 1 [illegible]).

C: [illegible] 1 [illegible] 2 [illegible] 0.05 [illegible] 1 [illegible] R [illegible] R [illegible] (~260 [illegible]) TS [illegible]

ÛõÅ ̧ Ō ̧ 20ş TS (ȯ/ȟ130~) ŌÅḀ̀Åõä Ȑϸ ȸ ̧ Ō ̧ 2 ȸ ̧ ǰÅÂ ̧ Ž ȟ0.07 ā äØÅ :**Chlorides** ğ äÆÅøźŸÒöä
"Limit test for Chlorides ğ äÆÅøźŸÒöä ŌDZɉ ɃÆΣä øḀ̊̇ǹɍä" ɉäźÅɜ ǨƠ Ȣźòź ̧ źȽ ÅȶÕ ŌȶȞöä ŌȶÒ̥ÊÅş
.ȟ/ȠŸ ̧ 3.5 ȸɜ ÆÅøźŸÒöä ɁźǪȚ ÆÅÂÅ ɍ Ü(124 ǦƜÅÔöä Û1 ÆŸǑä)

øḀ̊̇ǹɍä" ɉäźÅɜ ǨƠ Ȣźòź ̧ źȽ ÅȶÕ ŌȶȞöä ŌȶÒ̥ÊÅş öÅ ̧ Ō ̧ 20 Ž ȟ 0.05 ā äØÅ :**Sulfates** ğ ÅÅŸÊöä
.ȟ/ȠŸ ̧ 10 ȸɜ ğ ÅÅŸÊöä ɁźǪȚ ÆÅÂÅ ɍ Ü(125 ǦƜÅÔöä Û1 ÆŸǑä) "Limit test for Sulfates ğ ÅÅŸÊöä ŌDZɉ ɃÆΣä
ÛǴ ̀ÌÀÅ ÛTS (ȯ/ȟ420~) ŌÅøźŸÕşøÆÆTä Ȑϸ ȸ ̧ Ō ̧ 2 ȢÅȒÅ ÛöÅ ̧ Ō ̧ 10 Ž ȟ 0.10 ā äØÅ :**Zinc** ŌφÂöä
.gÀ ̀ÌÅǦ ̧ ǦæÅèɓ şÜ ÀȮɜ ǰ̥ÅÅɍ ÜTS (ȯ/ȟ45~) ÿźÆèÅǩźǦöä ÆÆφÅÆèşǨź ȯźŸȚ ȸ ̧ Ō ̧ 0.1 ȢÅȒÅş

ȯźŸȚ ȸ ̧ Ō ̧ 10 Ž ȟ 0.20 ā äØÅ :**Chloroform-soluble matter** ÿøźźşøźŸÒöä Ž Ǧææşǿöä gåÅȶä
ȤÅΘ ÛŌÔÅÅÆö ŌḀ̀Å .R ÿøźźşøźŸÒöä ȸ ̧ Ō ̧ 10 ǦÛèäźæ ȬŸḀ̊́ÊÅş VS (ȯ/ȯź ̧ 0.1) ÿźÅǻźÔöä ÆÆÊŌşøÆÆȽ
ȴè 1 ǦφÅǺǯæ gKDzǵ ȯŸǹ ȸ ̧ ǦǵÅ ̀ÌÀŸö ȋ ÅȶǪöä āÅŌÅ .ǴÌ ̀ÀÅş ÛR ǦÆəÅ ̧ Ÿöä ÿźÅǻźÔöä ğ ÅÅŸè ȧźź ÿøźźşøźŸÒöä ǦŌǦù
.0.10 ȸɜ ȋ ÅȶǪöä ÆÅÂÅ ɍ ÜR ÿøźźşøźŸÕ ɁźƠ ÆÅØ ̧ gKDzǵ ŌæÅŌ ̧ Ḁ̀ ̧ źφÅφ 480 ɄȶȚɜÜ ǦDZź ̧ ȯźÛæ

1 gÆ ̧ (ȯ/ȟ750~) ȯźφÅǯÅÜ Ō ̧ 20 ɜ ̧ ȟ0.2 ɁŸȢÅ :**Ethanol-insoluble matter** ȯźφÅǯÅɋä Ž Ǧææşæ Ÿöä gåÅȶä
ɁøǪǵ TS (ȯ/ȟ750~) ȯźφÅǯÅɋÅæ Ǵä ̀ÀȶäŌÊȢÅ ÛSintered glass filter ÀĐźƜȶä ǯÅDZÂöä Ǵä ̀ÀÅ ̧ Ǝɜ ǴÌ ̀ÀÅ ÛǦŌÆęǻ
.ȠŸ ̧ 2.0 ȸɜ ǦöÅȶǯöä ÆÅÂÅǩɍ Ü ɉäźÅş Ǧɜ Åè 1 gÆ ̧ °ÿ 105 ǦDZøÆöÅæ Ǵä ̀ÀȶäȤÅƶ ÛǦÅÀŌǨ ɉźŸöä ǦƹÆɜ ǴǦÔǨ

100 ȸ ̧ ÀǯŌÜ ÆŌÅÅ ɍ Ü°ÿ 105 gøäÀǵ ǦDZøÆæ ǨæÅǯöä ɉäźöä ɁøǪǵ ȤÅƶ :**Loss on drying** ȤÆÅDz̥ŌÅæ ÆŌÅöä
.ȟ/ȠŸ ̧

.9.0-7.0 Ûɉ źæÀÒöä ÆÆÊŌÅ ɄəÅÅǪ ȸ ̧ ƂÅƪ ä öÅȶä Ž Ō ̧/ȠŸ ̧ 20 ÂÆŌḀ̀æ ȯźŸɇä öÅȽÅæ ȠŸǦÅ :**pH Value** öÅȽÅǦöä ǦȶÆę

āäÀÎ̥èɍä" ɉäźÅɜ ǨƠ Ȣźòź ̧ źȽ ÅȶÕ øḀ̊̇ǹɍä ɁÅƶ :**Dimethyl formamide** ÆÆȠÅ ̧ øźź ŌÆǯÆ ̧ ɄəÅÅǪ
ȸ ̧ ǰÅÂ ̧ ȸ ̧ internal standard ɄŸǹäǻ ɃøÅÆȞ ̧ ÀȒɜ .(101 ǦƜÅÔöä Û1 ÆŸǑä) "Gas chromatography ɃäÅȢöä
ǰÅÂ ̧ (1) :ǦÆöḀ̊öä ǦǪŸǯöä ŌÆöÅ ɇä ȸŌƜɬ .öÅ ̧ Ō ̧ 100 Ž dimethylacetamide R ÆÆȠḀ̊Æè Ü ŌÆǯÆ ̧ ɃÆöä ȸ ̧ Ḁ̀öşÀÒ ̧ 20
ƙÆȞǨ ǦÆȢæ (2) ÜɄŸǹäÆöä ɃøÅÆȞȶä ȯźŸȚ ȸ ̧ Ō ̧ 10 ɃźƷş öÅ ̧ Ō ̧ 10 Ž R ÆÆȠÅ ̧ øźź ŌÆǯÆ ̧ ɄəÅÅǪ ȸ ̧ Ḁ̀öşÀÒ ̧ 2 ȸ ̧
ŌÅÀƜ̥öä ɜ ̧ ȢÅȒÅ ÛöÅ ̧ Ō ̧ 10 Ž øḀ̊̇ǹɍä gåÅ ̧ ȸ ̧ ȟ 1.0 ā äØÅ ÛǦòźƜÅȶä gåÅȶä retention time āḀ̊ǵä ȸ ̧ à
ȸ ̧ ȟ 0.1 ā äØɬ Ż ÛØÆÅɬ ÛǦŌÆęǻ 15 gÆ ̧ øäÀŌ̥èŸö ŌḀ̀Å ÛVS (ȯ/ȯź ̧ 0.5) ŌÅøźŸÕşøÆÆTä Ȑϸ ȸ ̧ Ō ̧ 10
ȯźŸȚ ȸ ̧ Ō ̧ 10 Ž øḀ̊̇ǹɍä gåÅ ̧ ȸ ̧ ȟ 1.0 ā äØÅ (3) ÜŽÅÛöä ŌəÅÊöä ȸ ̧ Ō ̧ 5 Ž R ÿźÅǻźÔöä ǦÆǪŸǪ ğ ÅÅÊÅöä
gÆ ̧ øäÀŌ̥èŸö ŌḀ̀Å ÛVS (ȯ/ȯź ̧ 0.05) ŌÅøźŸÕşøÆÆTä Ȑϸ ȸ ̧ Ō ̧ 10 ŌÅÀƜ̥öä ɜ ̧ ȢÅȒÅ ÛɄŸǹäÆöä ɃøÅÆȞȶä
.ŽÅÛöä ŌəÅÊöä ȸ ̧ Ō ̧ 5 Ž R ÿźÅǻźÔöä ǦÆǪŸǪ ğ ÅÅÊÅöä ȸ ̧ ȟ 0.10 ā äØÅ Ż ÛØÆÅɬ ÛǦŌÆęǻ 15

[illegible] 4 [illegible] 1.5 [illegible] silanized diatomaceous [illegible] 9 [illegible] macrogol 1000R [illegible] 1 [illegible] adsorbent [illegible] 120 [illegible] acid-washed [illegible] support R [illegible] .flam ionization detector [illegible]

[illegible] peak [illegible] area [illegible] ratio [illegible] .1 [illegible]

Thin- [illegible] :**Resorcinol** [illegible] R1 [illegible] (84 [illegible] 1 [illegible]) "layer Chromatography [illegible] R [illegible] 4 R [illegible] 6 [illegible] 1.0 [illegible] (A) : [illegible] 5 [illegible] (o/o 0.5) [illegible] 10 [illegible] 10 [illegible] 10 R [illegible] 2.5 [illegible] (B) [illegible] 15 [illegible] 30 R [illegible] .A [illegible] B [illegible]

[illegible] :**Related substances** ([illegible]) [illegible] R1 [illegible] (84 [illegible] 1 [illegible]) "Thin-layer chromatography [illegible] 2 R [illegible] 8 [illegible] 0.1) [illegible] 5 [illegible] R [illegible] 20 [illegible] :(B) [illegible] 1 [illegible] 10 [illegible] :(A) [illegible] (o/o [illegible] 1 [illegible] A [illegible] 30 R [illegible] .B [illegible]

:**Assay** [illegible]

[illegible] (o/70~) [illegible] 5 [illegible] 20 [illegible] 0.5 [illegible] R [illegible] -2 [illegible] 20 [illegible] 5 [illegible] 10 [illegible] .R [illegible]

[illegible] (~750) [illegible] 10 [illegible]
[illegible] 105 [illegible] 1 [illegible] 1.132 [illegible] $C_{20}H_{10}Na_2O_5$.

[illegible]

Additional requirement for Fluorescein sodium for sterile use

test for sterilty of non- [illegible] "injectable preparations [illegible] 5 [illegible] 32 [illegible].

ØØØØØ

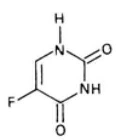
FLUOROURACILUM

Fluorouracil [illegible]

$C_4H_3FN_2O_2$:**Molecular formula** [illegible]

130.1 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

5-Fluorouracil; 5-fluoro-2,4(1*H*,3*H*)-pyrimidinedione; CAS Reg. No. 51-21-8.

[illegible] :**Description** [illegible]

[illegible] (~750) [illegible] :**Solubility** [illegible]
[illegible] R [illegible].

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

[illegible] 282 [illegible] :**Additional information** [illegible]

[illegible]

REQUIREMENTS [illegible]

[illegible] %98.5 [illegible] **General requirement** [illegible] $C_4H_3FN_2O_2$ [illegible] %101.0 [illegible]

Identity tests [illegible]

- [illegible] A [illegible] D, C, B [illegible]

A: [illegible] "Spectrophotometry in the infrared region" [illegible] RS [illegible] *reference spectrum*.

B: [illegible] 10 [illegible] 4.7 TS [illegible] 220 [illegible] 350 [illegible] qualitatively similar [illegible] 10.0 [illegible] 4.7 TS [illegible] RS [illegible] 266 [illegible] 232 [illegible] 266 [illegible] 1 [illegible] 0.54 [illegible] %3 [illegible]

C: [illegible] 0.5 [illegible] TS [illegible] 5 [illegible] 3 [illegible] 5 [illegible]

D: [illegible] 0.05 [illegible] 5 [illegible] 1 [illegible] TS1 [illegible]

Heavy metals [illegible] 1.0 [illegible] "Limit test for heavy metals" [illegible] 3 [illegible] 1 [illegible] 127 [illegible] A [illegible] 1 [illegible] 128 [illegible] 20 [illegible]

Sulfated ash [illegible] 1.0 [illegible]

Loss on drying [illegible] 80 [illegible] 0.6 [illegible] 5 [illegible] R [illegible] 4 [illegible] 5.0 [illegible]

ǦŐĒęÀöä ǦŐĢÛöä āäÀÎęèä" ȷäȥĀȝ ǨƠ 8ȥòȥȠ ȥŁ Àŧõ øÀĢęǹŗä ʔÀƶ :**Related substances** ǦŏÀÎţä ǻäȥţä ǦĦŊĒÀÔöä ǼĤǩ) ǦŸǧ8ȠǥǻÀŧõ R6 ÀÒĒŸĒÊöä ǦȠ¥Ł ÿäǼǺęèÀǣ Û(84 ǦĦŊÀÔöä Û1 ǼŸŎä) "Thin-layer chromatography ÛR òȥǷÀǯĒţä ȡȠ ÀŧDzǵ15 ÛR ǧÀęĒèÜ ŌĒǯÀÜ ȡȠ ÀŧDzǵ 70 ȡȠ ǰÀÂȠş (Ǧŧǝ¥Ƞ ɃøÀΘ øǼÔȠ ɃÜ ȡȠ ÀÕäÀè Ǧ¥8ţä ÿȥDzΣä òǻÀĤęȠ ǰÀÂȠ Ž ƙÀęä ƙòȥŸƮ ȡȠ ÀęöşÀÒȠ 5 ǦĦŊĒÀÔöä ʔŸȝ ŸÔÀÂȠ ĘǦÛÀ .ōÀĦŊęȠ øȥÛõ ŏÀţä ȡȠ ÀŧDzǵ15ş ȡȠ ȠŸȠ 0.050 Ƀȥȝ :(B) òȥŸǂäş ŌȠ 1 Ōõ Ž øÀĢęǹŗä ǥǻÀȠ ȡȠ ȠŸȠ 20 Ƀȥȝ :(A) òȥŸǂä ÛR òȥǷÀǯĒţäş ŏÀţä ȡȠ ÒĦŊÀłş ŏäȥTä Ž ȤDzęö ōÀęł Ûāä Î ęèŗä ǥƘDzǵ ȡȠ ǦĦŊĒÀÔöä ţÂę ǼĤäş .ŌȠ 1 Ōõ Ž RS ŌĒèäøȥÀşøȥŸÀöä ŏÀǯęèÀǣ ÛA òȥŸǂä ȡȠ ǰęÀǩ ǦĤŌǣ ǦÀÜ ȷȥÒǩ ŗ .(ÀęȠȥǷÀę 254) ǦĒDzÊÀÀĢöä ȧȥȥ ǦĤÌǰä ŏȥȑ Ž āäÀÎęèŗä ÙÛƯ .B òȥŸǂä ȡȠ ǦΘÀÀöä ŌŸǩ ȡȠ ǥǼÌ ÀǯōÜ ÛǦĒÊĒǝÀöä ǦĤŌĢöä

ƙDzÊōǰä ǦŸDzȥǵ ǦŌÀÀù" ȷäȥĀȝ ǨƠ 8ȥòȥȠ ȥŁ Àŧõ ȧäÀęǵŗä ʔÀƶ :**Fluorine content** øȥŸÀöä ʔȥęƮ ȡȠ ȠŸȠ 15 ǦäÀę 8ÀȒÀş ÛøÀĢęǹŗä ǥǻÀȠ ȡȠ ȠŸȠ 7 ÿäǼǺęèÀǣ Û(132 ǦĦŊÀÔöä Û1 ǼŸŎä) "oxygen flask method ŌŧęÒǩ ÀȠǼÀȝ . ǐ ÀȠ ŌǝÀÊõ VS (ȯ/ȯȥȠ 0.1) ÿȥÀǻȥÔöä ǼĒÊōşøǼĒŁ òȥŸƮ ȡȠ ŌȠ 15ş R ÿȥÀǻȥÔöä ǼĒÊōşƘǣ ŌȠ 100 ƂÜ ǧÀȥęǂä ȤÀƠ Ż ÛǥÀęÀö ǥÀęȥ ȡȠ ȒȴäȝȠ ĘǝÀęǻ 10 ȡȝ ŌŌǩ ŗ ǥǼȠ ǻȥōÀŸö ǦŸDzȥΣä ōÀęǩ ÛǦĒŸŧĤöä Oxygen ƙDzÊōşǰä ǦŸDzȥǵ ǦŌÀÀù" ȷäȥĀȝ ǨƠ 8ȥòȥȠ ȥŁ ÀȠ ǼÊŒ ŌȠ 5.0 ÿäǼǺęèÀǣ ǦĒŸŧĤöä ŌŧÒęÊǩ .ŏÀţÀǣ .F ȡȠ ÿäÀȡşÀÒȠ 55 ȡȝ ǼÀÀ ŗ Ü(132 ǦĦŊÀÔöä Û1 ǼŸŎä) øȥŸÀöä ƙĒĤǩ ŌDzǰ "flask method

:**Assay** ǦÊÀÀŌţä

òȥŸƮ ȡȠ ŌȠ 0.25 8ÀȒÀ ÛR ǼĒȠÀȠøȥȥ ŌĒǯĒȠ ɄǝÀÀę ȡȠ ŏÀȠ ŌȠ 80 Ž ÛǦĒùȥǦȒȠ ǦęşäȥȠ Ûȟ 0.4 ǦäÀę āäØÀ ʔøęǵ VS (ȯ/ȯȥȠ 0.1) ÿȥĒęȥȠÜ ŌĒǩȥäÀęęöä ǼĒÊōşøǼĒŁ òȥŸĦŊ ÀÀĤÀş TS ǼĒȠÀȠøȥȥ ŌĒǯĒȠ ɄǝÀÀę/òȥŧĒǯöä Ǧęøà Û"Non- aqueous titrationɄǝÀȠ¥öä Ùèȥöä Ž ǥÀÀĤţä" ȷäȥĀȝ ǨƠ 8ȥòȥȠ ȥŁ Àŧõ ǦÀǮÀöä ǦÛŌÀö ȧøàǰä ȷȥŸöä ŏżÀÒÀ VS (ȯ/ȯȥȠ 0.1) ÿȥĒęȥȠÜ ŌĒǩȥäÀęęöä ǼĒÊōşøǼĒŁ òȥŸƮ ȡȠ ŌȠ 1 Ōõ .(142 ǦĦŊÀÔöä Û1 ǼŸŎä) B ǦŌÀÀÛöä .$C_4H_3FN_2O_2$ ȡȠ ȠŸȠ 13.01

Ǐǖøƽϴǁ ǖƑDzŷǂƨǘǁ ǹȳǂŽǁ ǖǐƨƐǷNJǐNJǷNJǂƻǁ ǖǕǓ ƕǐǯƑƮǝ ǀƑǂƱǂDZ

Additional requirement for Fluorouracil for parenteral use

.(56 ǦĦŊÀÔöä Û4 ǼŸŎä ÀȚęä) "*Parenteral preparations* ǦĒÀŌΣä ǧäÀȒĦŊęÊţä "øǣ ǦōÀȴä ǥǻşÀȥȼö ǼĒDzęÊǩ ȷäȥĀȝ ǨƠ 8ȥòȥȠ ȥŁ ÀȠ ǼÊŒ øÀĢęǹŗä ʔÀƶ :**Bacterial endotoxins** ǦĒȠȥęÀƨä ǦĒŸǹäǼöä ǧÀęÀÀÀØöä ǦĤĢÛöä Ž 30 ǦĦŊÀÔöä Û5 ǼŸŎä) "test for Bacterial endotoxins ǦĒȠȥęÀƨä ǦĒŸǹäǼöä ǧÀęÀÀÀØöä ŌDzǰ øÀĢęǹŗä" .ȠŸȠ 1 Ōõ Ž RS ɄŸǹäǼöä ȷÀÀØöä ȡȠ ǦĒöşǻ ǥǼǵş 0.33 ȡȠ ÀǯōÜ Ƀȥȝ ŗ Ü(ǦÀÂĒŸƠǭä

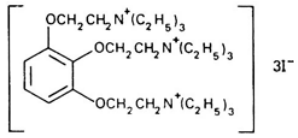
CALLAMINI TRIETHIODIDUM

Gallamine triethiodide [illegible]

$C_{30}H_{60}I_3N_3O_3$:**Molecular formula** [illegible]

891.5 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

[*ν*-Phenenyltris(oxyethylene)]tris[triethylammonium] triiodide; 2,2′,2′′-[1,2,3-benzenetriyltris(oxy)]tris[*N*,*N*,*N*-triethylethanaminium triiodide; 1,2,3-tris(2-diethylaminoethoxy)benzene triethiodide; CAS Reg. No. 65-29-2.

[illegible] :**Description** [illegible]

[illegible] (~750) [illegible] :**Solubility** [illegible]

[illegible]

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

.hygroscopic [illegible] :**Additional information** [illegible]

REQUIREMENTS [illegible]

[illegible] %98.0 [illegible] :**General requirement** [illegible]

[illegible] $C_{30}H_{60}I_3N_3O_3$ [illegible] %101.0

:**Identity tests** [illegible]

- [illegible] A [illegible] B [illegible] C [illegible] D [illegible]

A: [illegible] "Spectrophotometry in the infrared region [illegible] 43 [illegible]

[illegible] RS [illegible]

. ƙ ŋ ɍ Ȧ8öä ÆΛấ ʐ Ě ʒ ΛȀ ʒ Ÿö *reference spectrum* ɄȞDZȀ ʈ ä

Ȧ ŋ ÆΛ ʒ Û VS (ȯ/ȯ ʐ ŋ 0.01) ÕΛø ʐ Ÿ õ ş øÆ ŦTä Ȑ ƥ Ž Ō ŋ/ ÿäȀ ɖ ş Ȁ Ȯ ŋ 10 ÂĔ õȀ Ọ ä ȯ ʐ Ÿ ǂ î ȦÔỌ ŋ ɍ ä Ʒ Ě ù ɃÆ ǤΛ :B

ȷ ʐ ȮΛ ÜȀỌ ŋ ʐ φȦ φ 225 ǦäȀ ę ǦDZ ʐ ʈ ä ȯ ʐ ù Ž ȂĔ ʈ Ț ʒ Ǖ ȂòȦÔỌ ŋ ä ȀỌ ŋ ʐ φȦ φ 350ş ȀỌ ŋ ʐ φȦ φ 220 ƙ ä ʒ ä ʐ ŋ ɉ ä ȯä ʐ ùǕ Ž ÆĿȦÎΛ

.0.55ş 0.50 ƙ ä äØĿ ǦDZ ʐ ʈ ä ȯ ʐ ù Ž ɭ è 1 ǦφȦ Ấ ʒ ä ǦÕǦÛö î Ȧ ʈ Ọ ä

ȷ ʐ Ÿ ä ǦäȦ è ƅ ǰ ỌȂ Ǩ Üpotssio-mercuric iodide TS ȯ ʐ Ÿ Ț ȡ ŋ Ō ŋ 1 ȣ ȦȐΛ ş ǒȦ ŋ Ō ŋ 5 Ž ȟ 0.05 ā äØΛ :C

.ȀȦòǕ

General Ǧ ŋ ȦȞ öä ȣ äȀȞỌ è ɍ ä ğ äøȦǤỌ ǹ ä" ȷ ä ʐ Λ ʒ ǨƠ ȣ ʐ ò ʐ ʈ ä A Ō ʒ ȦȀỌ öä Ō ŋ/ ȟ 0.01 ÂĔ õȀỌ ä ȯ ʐ Ÿ ǂ ä ɄÛȞΛ :D

.(122 ǦɄȦÔöä Û1 ÆŸÕä) iodides ğ äÆΛấ ʐ ĔŸö ȂƀȶȠ Ō ʒ ȦȀỌ õ "identification tests

Ō ŋ 10 Ž ȟ 0.20 ÂĔ õȀỌ ä ȂDZäȦù ȀȐ ǂ ä ȯ ʐ Ÿ ǂ ä ȷ ʐ ȮΛ :**Clarity and colour of solution** ȯ ʐ Ÿ ǂ ä ȷ ʐ ö ş ǒȦȀò

Ȧ ŋ ÆΛ ʒ Yw1 ɃøȦĔȞ ʈ ä ȷ ʐ Ÿöä ȯ ʐ Ÿ Ț ȷ ʐ ö ǥÆ ì ȡ ŋ ƎõǕ ȼ φ ʐ ö ǥÆ ì ȷ ʐ Ȯ Ǩ ɍ ş ȂĔ ʐ Ȧò ȷ ʐ äȀȮöä ÆĔÊõǕ ɄəȦȀ φ ȡ ŋ ȯȦǹ ǒȦ ŋ

.(53 ǦɄȦÔöä Û1 ÆŸÕä) "colour of liquids ŌəäʐÊöä ȷ ʐ ö" ȷ ä ʐ Λ ʒ ǨƠ ȣ ʐ ò ʐ ŋ ʐ Ŀ Ȧ ʈ õ ȷ øȦÕΛ

.ȟ/ ŋ Ÿ ŋ 1.0 ȡ ʒ ÆΛȂΛ ɍ :**Sulfated ash** ǨȦŸÊ ʈ ä ấȦ ŋ Ȁöä

ȡ ŋ Ȁ ʒ õǕ ÆÕȂΛ ɍ Ü°ÿ 105 ǥøäȀ ǵ ǦDZøÆä ǨäȦ ʒ öä ȷ ȁ ʐ öä ʔ øỌ ǵ Ʒ Ȧ ƶ :**Loss on drying** Ʒ ĔȂDZỌöȦä ÆÕȂöä

.ȟ/ ŋ Ÿ ŋ 15

ȯ ʐ φȦ ʒ ΛǕ/ ŌĔ ʒ Ĕ ʈ ä ǥȀ ʈ ǵ ȯ ʐ Ÿ Ț ȡ ŋ Ō ŋ 0.2 ǒȦ ʈ ä ȡ ŋ Ō ŋ 50 ƂǕ ȣ ȦȐΛ :**Acidity and alkalinity** ǦΛ ʐ ŸÕöä ş Ǧ ȑ ʐ ʈ Σ ä

ÆĔÊõ ş øÆĔĿ ȯ ʐ Ÿ Ț ş Ǖ VS (ȯ/ȯ ʐ ŋ 0.01) ÕΛø ʐ ȦŸÊöä Ȑ ƥ Ȧ ŋ Ǖ Ǧ ʐ Ȧ ȑ Ǖ ǦÛè ä ʐ ä 6 ʔ øỌ ǵ ǒȦĿȦǤöä ȯÆȞ ƚ ş TS

ȐƐ ş Ǧò ʐ ɄȦ ʈ ä ǥấȦ ʈ ä ȡ ŋ ȟ 1.0 ȣ ȦȐΛ .ƂȦÕǨȀä - ȀȦòǕ ȷ ʐ ö ʔ Ÿ ʒ ȯ ʐ ÔΣ ä ʔ øỌ ǵ VS (ȯ/ȯ ʐ ŋ 0.02) ÿ ʐ Λấ ʐ Ôöä

ȯ ʐ Ÿ Ț ȡ ŋ ş Ǖ VS (ȯ/ȯ ʐ ŋ 0.01) ÕΛø ʐ ȦŸÊöä Ȑ ƥ ȡ ŋ Ȧ ŋ Ǖ Ō ŋ 0.2 ȡ ŋ Ȁ ʒ õǕ Ȁ ŋ ɉ ä ÆŸÛỌΛ ɍ Ü ā ş ØǨ ʔ øỌ ǵ

.ȼÊȦ φ ɄŸò ɉ ä ƂȦÕǨƎöä - ȀȦò ɉ ä ȷ ʐ Ÿöä ʔ Ÿ ʒ ȯ ʐ ÔɄŸö VS (ȯ/ȯ ʐ ŋ 0.02) ÿ ʐ Λấ ʐ Ôöä ÆĔÊõ ş øÆĔĿ

ǦÕĔ ę Ȁöä ǦÕǦÛöä ā äȀÎỌ è ä" ȷ ä ʐ Λ ʒ ǨƠ ȣ ʐ ò ʐ ŋ ʐ Ŀ Ȧ ʈ õ øȦǤỌ ǹ ɍ ä ʡ Ȁ ƶ :**Related substances** ǦòȦÎ ʈ ä ấä ʐ ʈ ä

ȡ ŋ ǰ ΛȂ ŋ ş ǦŸ ȹ 8 ŋ ǥấȦ ʈ õ cellulose R1 ȁ ʐ ö ʐ ŸÊöä ÿäÆẤỌ èȦä Û(84 ǦɄȦÔöä Û1 ÆŸÕä) "Thin-layer chromatography

ȨǤÛΛ .õȀɄỌ ŋ ø ʐ Ûõ R ȯ ʐ φȦ Ǩ ʐ ä-1 ȡ ŋ Ȃ ʈ DZ ǵ 66ş ǒȦ ʈ ä ȡ ŋ Ȃ ʈ DZ ǵ 17 ÛR ɄDZŸ ʒ öä ÕĔỌĔ è ɉ ä Ȑ ƥ ȡ ŋ Ȃ ʈ DZ ǵ 17

ŋ Ÿ ŋ 5.0 Ƀ ʐ Ʒ :(A) ȯ ʐ Ÿ ǂ ä ÛTS (ȯ/ȟ 750~) ȯ ʐ φȦ ʒ Λ ɋ ä Ž ƙ ȦỌ ä ƙ ö ʐ Ÿ Ț ȡ ŋ ÿäȀ ɖ ş Ȁ Ȯ ŋ 10 ǦɄĔȦÔöä ʔ Ÿ ʒ ȸ ŸÔȂΛ ŋ

õȀɄỌ ʈ ä ø ʐ Ûöä õȀỌΛ .Ō ŋ 1 Ōõ Ž øȦǤỌ ǹ ɍ ä ǥấȦ ŋ ȡ ŋ ŋ Ÿ ŋ 0.05 Ƀ ʐ Ʒ :(B) ȯ ʐ Ÿ ǂ ä ş Ō ŋ 1 Ōõ Ž øȦǤỌ ǹ ɍ ä ǥấȦ ŋ ȡ ŋ

ȯ ʐ ŸɄ ŋ æȀ ǩ ş ȡ ǹ ȦÊöä ǒä ʐ Tä ȡ ŋ øȦĔ Ǩ Ž Ʒ Ȧ Ɵ Û ā äȀÎỌ è ɍ ä ǥƘDZ ǵ ȡ ŋ ǦɄĔȦÔöä ʈ Ȃ φ ÆȞ ä .ɭ è 10 ʔ øỌ ǵ ấ ʐ ȞÔŸö

ȯ ʐ Ÿ ǂ ä ā äȀÎỌ è ä ÙÛƯ Ž ǦDZ ş ấȂ ŋ ȂŒäõ ş ş ÆǤǨ ȧ øȀǕ ȷ ʐ Ÿ ä Ǧö ş ȦÛỌ ŋ ǦȞÕä ŌÒÎỌ Ǩ .Potassium iodoplatinate TS

.B ȯ ʐ Ÿ ǂ ä ȡ ŋ ǦƟȦöä ÕŸ Ǩ ȡ ŋ ǥÆ ì Ȁ ʒ õǕ A ȯ ʐ Ÿ ǂ ä ȡ ŋ ǦƟȦöä ǦĔÊĔəȀöä ǦȞÕǦöä ȧ ʐ ʐ ǦȞÕä ǦΛǕ ȷ ʐ Ȯ Ǩ ɍ ş .A

:**Assay** ǦÊǁǺŐţă

ğǺǪĘèǛ ȯzǷŢ ȸŋ Ōŋ 15 ȣǺȒǁş ÛR ȷzǪèɉă ȸŋ Ōŋ 40 Ž ÛǦĘùzǦȒŋ Ǧǫşàzŋ Ûȟ 0.5 ǦăăǺę āăǾǁ zĿ Ǻŧõ ǼȚƨă âǺĘŌŋ ǦǁǺȚǺăă ǦÛŌǫ ȸĦǨş ÛVS (ȯ/ȯzŋ 0.1) ȬǁǿzǷõƘǦăă Ȑŧɯ ǺǁǺȞǁ .TS ȬĘǪèɉă Ȑþ/ĘǦəÂăă Û1 ǼǷŎă) A ǦŌǁǺÛăă ǼÊɯ Û"Non- aqueous titration ɄəǺŋƳăă Ȕèzăă Ž ǥǺǁǺȞţă" ȷăzǺȝ ǨƠ ȣzòzŋ .$C_{30}H_{60}I_3N_3O_3$ ȸŋ ŊǷŋ 29.72 ŏżǺǾǁ VS (ȯ/ȯzŋ 0.1) ȬǁǿzǷõƘǦăă Ȑþ ȸŋ Ōŋ 1 Ŏõ .(142ǦĦǺÔăă

ØØØØØ

GENTAMYCINI SULFAS

Gentamycin sulfate ǄžƨǊǄǰɈűɯǁɛ ǀƑƻƨ

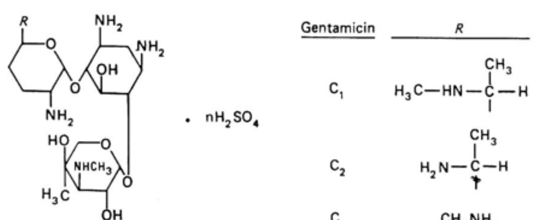
(**Non- injectable** ǄžŝƟƻǁ ɦƻǦǰŝǁɛ þǏȜ) ǄžƨǊǄǰɈűɯǁɛ ǀƑƻƨ

sterile ɦǄžǏŝƴǁɛ ÛǄžƨǊǄǰɈűɯǁɛ ǀƑƻƨ

Ǝȝ ǦǄzǷǺţă C1aş C2ş C1 ƙÊĘŋǺǪǁƨă ŏăÂǄZɉ ğǺǺǷÊăă ǴǷŋ ɄĿ ƙÊĘŋǺǪǁƨă ğǺǺǷè :**composition** ǼĘõȀǪăă

.*Micromonaspora purpura*; CAS Reg. No. 1405-41-0 ǦĘǫăzǄZǿǥă ǦǫǺȡzĘăă zʃ

:**Graphic formula** ǦĘǫǺĘǦţă ǦȣĘÔăă



.ǦĦəăȀăă ȻǼȝ ÜɄƸȀõ ƂǛ ȐĘăǛ ȷzǷă ɃǿzǷă ȧzĦÊŋ :**Description** Ȥòzăă

Ž ɍş R Ƙǭɉă Ž ɍş TS (ȯ/ȟ750~) ȯzǫǺǯǁqă Ž ǺĘǷŧȝ āăşǽ Ƙȡ ÜǑǺţă Ž āăşǽ :**Solubility** ǦĘǫǺǽşǾăă

.R ȳǿzzşǿzǷȮăă

.ǈĘǫăȀƨă ǻǺȒŋ ŏăşǻ :**Category** ǦǺǺăă

.ŏzȒăă ȸŋ ǦĘŧŢ ÛȳǺȮǵǖǽ ǦŌǷȣŋ Ǧǁşǻǵ Ž ƙÊĘŋǺǪǁƨă ğǺǺǷè ȘǺǵ Ǽƺ :**Storage** ȸǁÂǺǪăă

ğǺǺǷÊŏ ǦĘzǺȓqă ğǺǦǷÛǪţă ɄǿǦǷǨ ǥǻǺţă ȷǛ ƂǛ ǦŧĘŌȞăă ƙÊĘŋǺǪǁƨă ğǺǺǷè ǦŧĘÊǪăă ƘȊǨ :**Labelling** ǈĘèzǪăă

.ȿǺǹɉă ǦŧĘŌȞăă ğǺŌĘǦÛǪăă ŌǄZɉ şǛ ɄǿǺŌƩă ŏǺÛȝȒŏ ŌŧȞǪÊǨ ȷǛ ȸȮƸş ǦŧĘŌȞăă ƙÊĘŋǺǪǁƨă

ÛŏǿǾĘǪǨ hygroscopic ǦǦùȀǪÊŋ ǥǻǺŋ ƙÊĘŋǺǪǁƨă ğǺǺǷè ǼȞǩ :**Additional information** ǦĘzǺȓǛ ğǺŋzǷȞŋ

[illegible]

REQUIREMENTS [illegible]

[illegible] 590 [illegible] **General requirement** [illegible]

[illegible] 1 [illegible]

Identity tests [illegible]

"Thin-layer chromatography [illegible] A [illegible] R5 [illegible] (84 [illegible] 1 [illegible]) (260~) [illegible] 1 [illegible] R [illegible] 1 [illegible] R [illegible] 1 [illegible] TS [illegible] 20 [illegible] (B) [illegible] 1 [illegible] 20 [illegible] (A) [illegible] triketo [illegible] RS [illegible] 1 [illegible] 2 [illegible] °[illegible] 105 [illegible] hydrindene/pyridine/acetone TS [illegible] B [illegible] A [illegible]

General [illegible] A [illegible] 10 [illegible] B "identification tests [illegible] (123 [illegible] 1 [illegible])

Specific optical rotation [illegible] 0.10 [illegible] $[a]_D^{20°C} = +107$ to121° [illegible]

Sulfated ash [illegible] 10 [illegible]

Determination of water by [illegible] **Water** [illegible] "the Karl Fischer method [illegible] A [illegible] (145 [illegible] 1 [illegible]) [illegible] 0.2 [illegible] 150 [illegible]

pH Value [illegible] 40 [illegible] 3.5-5.5

Assay [illegible] "Microbiological assay of antibiotics [illegible] (155 [illegible] 1 [illegible]) [illegible] *Bacillus pumilus* (NCTC 8241; ATCC 14884) [illegible] *Bacillus subtilis* (ATCC 6633) [illegible] *Staphylococcus aureus* (ATCC 6538P) [illegible] Cm1 [illegible] 7.8 [illegible]

[illegible] 20 [illegible] 2 [illegible] TS2 [illegible] TS1 [illegible] 8.0 [illegible] 39-35 [illegible] 1 [illegible] %105 [illegible] %95 [illegible] estimated potency (P=0.95) [illegible] 590 [illegible] (P=0.95) [illegible] 1 [illegible]

[illegible]

Additional Requirements for Sterile for Gentamycin sulfate

Sterility testing of [illegible] :**S terility** [illegible] "antibiotics [illegible] (162 [illegible] 1 [illegible])

[illegible]

Additional Requirements for Gentamycin sulfate for sterile use

Test for sterility of non- [illegible] "injectable Preparations [illegible] 5 [illegible] 32 [illegible]

[illegible]

Additional Requirements for Gentamycin sulfate for parenteral use

[illegible] *Parenteral Preparations* [illegible] 4 [illegible] 56 [illegible]

[illegible] :**Bacterial endotoxins** [illegible] "Test for bacferial endotoxins [illegible] 5 [illegible] 30 [illegible] 1.70 [illegible] RS [illegible] 1 [illegible]

ØØØØØ

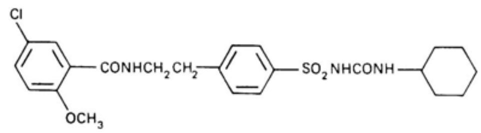
GLIBENCLAMIDUM

Glibenclamide [illegible]

$C_{23}H_{28}ClN_3O_5S$:**Molecular formula** [illegible]

494.0 :**Relative molecular mass** [illegible]

:Graphic formula ǦǦǦ ǦǦǦ



:Chemical name ǗǝǞǟ ǠǡǢ

1-[[*p*-[2-(5-Chloro-*o*-anisamido)ethyl]phenyl]sulfonyl]-3-cyclohexylurea; 5-chloro-*N*-[2-[4-[[[(cyclohexylamino)carbonyl]amino]sulfonyl]phenyl]-ethyl]-2-methoxybenzamide; 1-[4-[2-(5-chloro-2-methoxybenzamido)ethyl]-phenylsulfonyl]-3-cyclohexylurea; CAS Reg. No. 10238-21-8.

.ǦǦǦǦ ǦǦǦǦ ǦǦ ǦǦǦǦ ǦǦ ǦǦǦǦ Ȑ ǦǦ Ȑ ǦǦ ǦǦǦ ǦǦǦ **:Description** ǦǦǦ

TS (ȯ/ȟ750~) ǦǦǦǦ Ž ǦǦǦǦ ǦǦǦ ǦR ǦǦǦ Ž ǦǦ ǦǦ Ž ǦǦǦ ǦǦǦ ǦǦ **:Solubility** ǦǦǦǦ

.R ǦǦǦǦǦ Ž ǦǦǦǦ ǦǦǦ ǦR ǦǦǦǦǦ

.ǦǦǦǦ ǦǦǦ ǦǦǦ **:Category** ǦǦǦ

.ǦǦǦ ǦǦǦǦ ǦǦǦǦ Ž ǦǦǦǦǦ ǦǦǦ ǦǦ **:Storage** ǦǦǦǦ

REQUIREMENTS ǦǦǦǦ

%101.0 ǦǦ ǦǦǦǦ ǦǦ %98.5 ǦǦ ǦǦǦ Ǧ ǦǦ ǦǦ ǦǦǦǦǦ ǦǦǦ **:General requirement** ǦǦǦ ǦǦǦǦ

.ǦǦǦ ǦǦǦ ǦǦ ǦǦǦǦ ǦǦǦǦ Ǧ$C_{23}H_{28}ClN_3O_5S$ ǦǦ

:Identity tests ǦǦǦǦ ǦǦǦǦ

• ǦǦǦ ǦǦǦǦ ǦǦ A ǦǦǦǦ ǦǦǦ ǦǦ B ǦǦǦǦ .CǦ

ǦǦǦǦ ǦǦ ǦǦǦǦ ǦǦǦǦ Ž ǦǦǦ ǦǦǦ ǦǦǦ" ǦǦǦ ǦǦ ǦǦǦǦ ǦǦ ǦǦǦ A ǦǦǦǦ ǦǦǦ :A
ǦǦ ǦǦǦǦ Ž ǦǦǦǦǦ ǦǦ ǦǦǦǦ .(43 ǦǦǦǦ Ǧ1 ǦǦǦ) "Spectrophotometry in the infrared region
.ǦǦǦǦǦǦ *reference spectrum* ǦǦǦǦ ǦǦǦ ǦǦ ǦǦǦǦǦ RS ǦǦǦǦǦǦ ǦǦ ǦǦǦ ǦǦǦ ǦǦ ǦǦǦǦ

ǦǦǦǦ ǦVS (ȯ/ȯǦ 0.01) ǦǦǦǦǦǦ Ȑ Ǧ Ž ǦǦ/ǦǦ 0.10 ǦǦǦǦ ǦǦǦ ǦǦǦǦǦ ǦǦ ǦǦǦ :B
ǦǦǦǦ ǦǦǦǦǦ ǦǦǦǦ 230 ǦǦǦ ǦǦǦǦ ǦǦǦǦǦ ǦǦǦǦ 350Ǧ ǦǦǦǦ 230 ǦǦ ǦǦǦǦ ǦǦǦǦ Ž ǦǦǦǦ
.0.63 ǦǦǦ ǦǦǦǦ 300 ǦǦǦǦ ǦǦǦ Ž ǦǦ 1 ǦǦǦǦ ǦǦǦǦ ǦǦǦ ǦǦ ǦǦǦǦ ǦǦǦ ǦǦǦǦ 275 ǦǦǦ ǦǦǦ ǦǦǦǦ

.°ȳ 172 ǦǦǦ ǦǦǦǦǦ ǦǦǦǦ ǦǦǦ :C

ǦǦ ǦǦǦǦ ǦǦ ǦǦǦ ǦǦǦǦǦ ǦǦǦ ǦǦǦ ǦǦǦ ȟ1.0 ǦǦǦǦǦ **:Heavy meatals** ǦǦǦǦ (ǦǦǦǦ) ǦǦǦǦ

Û1 ÆŸÕ) 3 ŏäÀDZqā ÆÊШ Û"Limit test for heavy metals ĞŸÊÕ̃ŏä (ğāÀŸÀŏä) յåĤţā ŌDZɉ ɃÆΣā øĠnɼā" յāζʒ .ȟ/ȳäÀʠşÀÒŋ 20 ȸʒ ÆÂÂ ɼ Ü(125 ĞǶÀÔŏä

.ȟ/ŋŸŋ 1.0 ȸʒ ÆÂÂ ɼ :**Sulfated ash** ǨÀŸÊţā åÀŋÀŏä

10 ȸŋ Àǯõ̃Ü ÆÕÀÂ ɼ Ü°ȳ 105 ǥøäÀǵ ĞDZøÆä ǨäÀǯŏä յàζŏä ʔøǫǵ ȤÀƶ :**loss on drying** ȤÊÀDZǫŏÀä ÆÕÀŏä .ȟ/ŋŸŋ

ČÕÊęÀŏä ČÕĜÛŏä āäÀÎǫèā" յāζʒ ǨƠ ȣζòζŋ ζŁ Àŧõ øĠnɼā ĘĜÛÂ :**Related substances** ĞŏÀÎţā åäζţā 45 ȸŋ ǰÂŋş ČŸǰȣŋ ǥåÀŧõ R4 ÀÒÊŸÊÊŏä ĞŋƳŁ ȳäÆǺǫèÀä Û(84 ĞǶÀÔŏä Û1 ÆŸÕ) "Thin-layer chromatography ȳζDZǵ 5ş ÛTS (ò/ȟ750~) òζǫÀǯÂqā ȸŋ ȳζDZǵ 5 ÛR յÀÊÒŁζŸÒÊÊŏä ȸŋ ÀŧDZǵ 45 ÛR ȳøζζşøζŸÒŏä ȸŋ ÀŧDZǵ Ž ƙÀǫä ƙŏζŸꞆ ȸŋ ÀǫŏşÀÒŋ 10 ĞǶÊÀÔŏä ʔŸʒ ŸÔÀÀŋ ĘĜÛÂ .õ̃ÀǶǫŋ øζÛõ R ɄDZŸǯŏä Õ̃ÊǫÊèɉā Ȑþ ȸŋ ǥåÀŋ ȸŋ ŋŸŋ 0.05 Ƀζʒ :(B) òζŸŧāş Ōŋ 1 Ōõ Ž øĠnɼā ǥåÀŋ ȸŋ ŋŸŋ 10 Ƀζʒ :(A) òζŸŧā ÛR ȳøζζøζŸÒŏä āäÀÎǫèɼā ȔÛƯ ȎǶÀÂş ŏäζTā Ž ȤDZǫŏ õ̃ÀǫǨ Ûāä ÀÎǫèɼā ǥƘDZǵ ȸŋ ĞǶÊÀÔŏä ţÀǫ ÆĤä .Ōŋ 1 Ōõ Ž øĠnɼā ǥÆȉ Àǯõ̃Ü ÛČÊÊÊàÀŏä ČĤÕĜŏä ŏÀǯǫèÀä ÛA òζŸŧā ȸŋ ǰǫÀǨ ČĤÕä ĞÂÜ յζÒǨ ɼ .(Àǫŋζǫǫ 254) ĞÊDZÊÀÀĜŏä ȧζζ ĞĤȉɉā Ž .B òζŸŧā ȸŋ ĞΘÀÀŏä Õ̃ŸǨ ȸŋ

ÀÂÅĤÂş ÛTS ȸǹÀÊŏä òÆĤǫÊţā òζǫÀǯÂqā ȸŋ Ōŋ 100 Ž ÛČÊùζĜȒŋ Čǫşàζŋ Ûȟ 0.5 ĞääÀę āäøÂ :**Assay** ĞÊÂÀÕ̃ţā TS òζǫÀǯÂÜ/ƙÀÒÀǯζ òζÆÊÀŏä ȳäÆǺǫèÀä ÛVS (ò/òζŋ 0.1) ǧÀǫζāÀÒŏä ȸŋ ƃÀʅā ȳζÂåζÔŏä ÆÊÊõ̃şøÆÊŁ òζŸǶŋ ÆÊÊõ̃şøÆÊŁ òζŸꞆ ȸŋ Ōŋ 1 Ōõ .ČÂøşÀȓ ǧÀǶÊǶÒǨ ĞÂÜ ʔÀΘş ĞòζǶÀţā ǥåÀţā յşå ĞÊŸŧĤŏä åÀĤǨ .ÀĤÎŧõ .$C_{23}H_{28}ClN_3O_3S$ ŋŸŋ 49.40 ŏżÀÒÂ VS (ò/òζŋ 0.1) ǧÀǫζāÀÒŏä ȸŋ ƃÀʅā ȳζÂåζÔŏä

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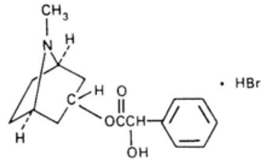
HOMATROPINI HYDROBROMIDUM

Homatropine hydrobromide DžǏĜǋǰþƗDŽǋǋǁǁ ǫǏDŽǋǰþĜǋǰþǫǏǈǰ

$C_{16}H_{21}NO_3$,HBr :**Molecular formula** ĞÊÅÂÂƨā Ğ8ÊÔŏä

356.3 :**Relative molecular mass** ĞÊĜÊÂŏä ĞÊÅÂÂƨā ĞŸǫÒŏä

:**Graphic formula** ĞÊǫÀÊĜţā Ğ8ÊÔŏä



Chemical name:

1α*H*,5α*H*-Tropan-3α-ol mandelate (ester) hydrobromide; (±)-*endo*-8-methyl-8-azabicyclo[3.2.1]oct-3-yl α-hydroxybenzeneacetate hydrobromide; CAS Reg. No. 51-56-9.

Description:

Solubility: (~750) TS ... R ... R.

Category: Mydriatic.

Storage:

REQUIREMENTS

General requirement: %98.0 ... $C_{16}H_{21}NO_3,HBr$ ... %101.0.

Identity tests:

A: 10 ... 1 ... (~100) TS ... 5 ... R ... 1.5 ... TS ...

B: 20 ... A ... General identification tests ... bromides (120 ... 1).

C: 215 ...

Sulfated ash: 1.0 ...

loss on drying: 105 ... 15 ...

pH Value: 20 ... 5.5-7.0.

Foreign alkaloids: 10 ... 2 ... 0.25 ... TS (50) ...

Related alkaloids: 5 ... 0.25 ... R ...

ÆĿÊÕşøÆĿŁ ȯǶŸŢ ȸȠ ǺŧǅǵǴ 1 ȸȠ ǰǺÂȠ ȸȠ ǑȠ 0.1ş R ȷǶǪĿèǰ ȸȠ ǑȠ 0.1 ȣÅR̂Ǻş ǻƎĿö ȭÀǪǺ .ȹǝÅȠ ȳÅƥ ɂŸȝ ȷǶö ɃǕ ǰǪǺǺɍ ǕTS (ȯ/ȟ750~) ÆĿŁÆöǰ ȸȠ ƃÅȴ ȯǶǷÅǯǺqǰ ȸȠ ȳǶǅǵ 4ş VS (ȯ/ȯǶȠ 0.5) ȯǶǷÅǯǺǕ/ȳǶĿèÅǩǶǤöǰ
.ÀƥǪö ǡøÅȓ ɄǅÊÀǺæ şǕ ɄǅÊÀǺæ

ǑȠ 10 ȣÅR̂Ǻ ǕR1 ɄǅŸǯöǰ ǬĿǪĿèǰ R̀ƥ ȸȠ ǑȠ 30 Ž ǕǦęÆæ ǦƥşàǶȠ Ǖȟ 0.3 ǦǟǰÀę ǡǰǾŀ :**Assay** ǦÊǺÅǬţǰ
ǦǺÅŢǺöǰ ǦǕǑƥ ƙĿȞǩş ǕVS (ȯ/ȯǶȠ 0.1) ǬǺøǶŸȭƘǦöǰ R̀ŧɯ ÀǺÅȞǺş ǕTS ǬĿǪĿèǰ R̀ƥ/ĘǦǝÂöǰ ǧÅǪĿèǕ ȯǶŸŢ ȸȠ
A ǦǬǺÀǕöǰ Ǖ"Non-aqueous titration ȹǝÅȠŸöǰ Ǖ̀èǶöǰ Ž ǥÀǺÅȞţǰ" ȷǰǶǺȝ ǨƠ ȣǶòǶȠ ǶŁ ÅŧȭÆŢƨǰ ǡÅĿǑȠ
$C_{16}H_{21}NO_3$,HBr ȠŸȠ 35.63 öŻÅǾǺ VS (ȯ/ȯǶȠ 0.1) ǬǺøǶŸȭƘǦöǰ R̀ƥ ȸȠ ǑȠ 1 Ǒȭ .(142 ǦȞÅÔöǰ Ǖ1ÆŸǾöǰ)

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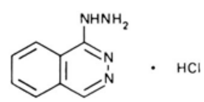
HYDRALAZINI HYDROCHLORIDUM

Hydralazine hydrochloride ǄǮŘŰƐƥǫǏǇǁƐ ǫǏƥǊǂǀǋƥǫǏǉ

$C_8H_8N_4$,HCl :**Molecular formula** ǦĿÅǺÂƨǰ ǦȣĿÔöǰ

196.6 :**Relative molecular mass** ǦĿǦÊÀöǰ ǦĿÅǺÂƨǰ ǦŸǪǾöǰ

:**Graphic formula** ǦĿƥÅĿǦţǰ ǦȣĿÔöǰ



:**Chemical name** ȹǝÅĿŧĿǾöǰ ȴèɍǰ

1-Hydrazinophthalazine monohydrochloride; 1(2*H*)-phthalazinone hydrazone monohydrochloride; CAS Reg. No. 304-20-1.

.ǦȞǝǰÀöǰ ǇÆȝ ǕĿǦǺÀǑǨ R̀ĿæǕ şǕ R̀ĿæǕ ȷǶŸæ ɃøǶŸæ ȧǶȞÊȠ :**Description** ǫòǶöǰ

ǴĿȞì ǕTS (ȯ/ȟ750~) ȯǶǷÅǯǺqǰ Ž ȷÅæşǾöǰ ǴĿȞì ǕöÅţǰ ȸȠ ǼöÂǅ 25 Ž ǡǰşǽ :**Solubility** ǦĿƥÅæşǾöǰ
.R ƘǪǰ Ž ǼÆǅ ȷÅæşǾöǰ

.ȳÆöǰ Ǖ̀ȣR̂ö R̀ǶÅǹ öǰşǻ :**Category** ǦÅÀöǰ

.ǒǶR̂öǰ ȸȠ ǦĿŧŢ ǕǼÆǅ ǦǬŸȣȠ ǦǺşÅǵ Ž ȸǺàɍǰøÆĿTǰ ÆǺøǶŸȭşøÆĿŁ ȘÅǵ Æƶ :**Storage** ȸǺÂǺǪöǰ

.ǬǾÀǪöǰ ȝȠ °ȳ 275 ǦǟǰÀę ȸǺàɍǰøÆĿTǰ ÆǺøǶŸȭşøÆĿŁ ÀŢÔǺ :**Additional information** ǦĿǶÅȓǕ ǧÅȠǶŸȞȠ
ǧÅǅøǻ ÆǺȝ ţÀèǕ ȷǶǾǺ ǬǾÀǪöǰş ǕɃǶƨǰ ƥǺÅţǰ ǦæǶüÀö ȏÀȞǪöǰ ÆǺȝ ǼƶøÆǨ ǕǒǶR̂öǰ ǡÅĿȡ Ž ɂøǪǵ ǕȭǾÆǪş
.ɂŸȝǰ ǥøǰÀΣǰ

ā şǾǩ ɍ %98.0 ȸȝ ŌǾ ɍ Åņ ʡŸȝ ȸàɍāǿǼŢā ǼǿȥŸõşǿǼŁ Ƀȥǫʒ :**General requirement** ÿǨöā ǼŸÛǪţā
.ǦÀÀÕā ģåţā ƂǕ ţȥǅÀöǽ ǦǽȥÊȚ ÛC8H8N4,HCl ȸņ %101.0 ȸȝ

:**Identity tests** ƕĭǸǈǁ ľ ɛƥƑǴǪɛ

ÀǪņȥǿÀǾ 220 ƙǽ ǯāȥņɉā ȯāȥùǕ Ž ǼŁÎ Ǻ ÀņǼȝ ÛŌņ/ÿāÀȡşÀǪņ 10 ÂǼõÀǪǽ ȯȥŸǂ ɩ ÀÔǪņɍā ȤǼù ɃǼǦ :A
ǦǾǦù ȯƳǹ ȸņ ɩ ÀȶǪöā ŋŸǦ ÜÀǪņȥǿÀǾ 315ş Û303 Û260 Û240 ǯāȥņɉā ȯāȥùüǽ ǼȶȚȝǕ ǨòÀÔǪņā ÛÀǪņȥǿÀǾ 350ş
.ƃāȥǪöā ʡŸȝ Û0.21ş Û0.27 Û0.54 Û0.58 ǦǽāÀę ȻǾŁ ǯāȥņɉā ȯāȥùǕ Ž ȴè 1 ǦǿÀǺǯǽ

Ōņ 20 ȣÀȒǺ ÛTS (ȯ/ȟ70~) ŌǾǿȥŸõşǿǼŢā Ȑƥ ȸņ Ōņ 8ş ǒÀņ Ōņ 100 ȸņ ǰÀņ Ž ŋŸņ 0.5 ā āǾǺ :B
ǦǅǿǼǽ ȤÀΘş ǒÀţÀǽ ǦöÀȶǯöā ŌÊ8Ɨ .ǴìÀǺş ȨǝÀęǻ 10 ģǼņ ǻȥõÀŸö õÀǪǺ ÛTS (ȯ/ȟ10) ÿȥǺǻȥÔöā ǨǺÀǪǾ ȯȥŸȚ ȸņ
.°ÿ 210 ǦǽāÀę ǿÀȚÔǾqā ģǿāÀǵ ǦǅǿǼǻ Ü°ÿ 105

General ǦņÀǨöā ȣāÀǨǪèɍā ǵāǿÀǦǪǹā" ȷāȥǺȝ ǨƠ ȣȥòȥţā A ŌȝÀÀǪöā Ōņ/ŋŸņ 20 ÂǼõÀǪǽ ȯȥŸǂā ɄÛǨǺ :C
.(121 ǦǶÀÔöā Û1 ǼŸǑā) ǵāǼǺǿȥŸȮŸö ÂɃȶɧ ŌȝÀÀǪõ "identification tests

ÛŌņ 250 ȴǅǕ ǦǼùşÀƯ ǦŸǅȥǵ ƂǕ ȟ 2.0 ŌǾǺ :**Water-insoluble substances** ǒÀţā Ž ǦǽāşǽƳöā ǻāȥţā
ÀƉȥǂā ǯÀǅÂöā ǴǽÀɧ ǦǾǩȥǽ ȯƳǹ ȸņ ȯȥŸǂā ǴìÀǺ .ǦǾǼęǻ 30 ģǼņ ǦǼȮǼǾÀȮǼņ ŌǝÀèȥǽ ǯÀǺş ÛǒÀņ Ōņ 100 ȣÀȒǺ
ȴǅǕ ÀȚǺņ Ōõ ǒÀţā ȸņ ÿÀÊęǕ ǦǫƳǯǽ ǦöÀȶǯöā ŌÊ8ǩ .ǦǾǩȥǦöā Ōǹāǻ ā şǾǩ B ǦöÀȶǷ ǦǕ ŌÊ8ǩş ÛǦŸǅȥΣā ŌÊ8ǩ ÛȟÀÀţā
.(ȟ/ŋŸņ 5) ŋŸņ 10 ȸȝ ǦöÀȶǯöā ȷàş ǼÂǺ ɍ Üȷàȥǃş ǻƎǺ ÛǵÀȝÀè 3 ģǼņ °ÿ 105 ģǿāÀǵ ǦǅǿǼǽ ȤÀƶ ÛŌņ 10
.ȟ/ŋŸņ 1.0 ȸȝ ǼÂǺ ɍ :**Sulfated ash** ǨÀŸÊţā ǻÀņÀöā

0.6 ȸȝ ǼÂǺ ɍ) ȐÀǺÀņ Ǜ8ȓ ǨƠ ǦÛǂā ģǿāÀΣā ǦǅǿǼǽ ȤÀƶ :**loss on drying** ȤǼÀǅȥǪöǽ ǼǾÀöā
.ȟ/ŋŸņ 5.0 ȸņ ÀǰõǕ ǼǾǺ ɍ Üǵ ÀȝÀè 8 ģǼņ R ǿȥÀÊǼöā ǼǼÊõǕ ɄèÀȶȟ ȧȥȥ (ȨǦǝà ȴŸņ 5 ǦǽāÀę şǕ ȯÀǑèÀǽȥŸǼõ
ǦǾǼęÀöā ǦǾǦÛöā āāÀÎǪèā" ȷāȥǺȝ ǨƠ ȣȥòȥņ ȥŁ Àȶõ ǿÀǦǪǹɍā ʔÀƶ :**Related substances** ǦǒÀÎţā ǻāȥţā
ǦǤÊǼöÀǽş .ǦŸǬ8ņ ģÀȶõ R1 ÀǑǼŸǼÊöā ǦņƳŁ ÿāǼǺǪèÀǽ Û(84 ǦǶÀÔöā Û1 ǼŸǑā) "Thin-layer chromatography
ÿȥǅȥǵ 8ş TS (ȯ/ȟ260~) ÀǼȥņɉā ȸņ ǨȶǅȥǶ 2 ÛR ŌǼǰǺqā ǵÀǪǼèǕ ȸņ ǨȶǅȥǶ 2 ȸņ ǰÀņ ņȐƸ ÛõÀǶǪţā ǿȥÛŸö
ģÀņ ȸņ ȟ 0.10 ā āǾǺ ÛǿÀǦǪǹɍā ȯȥŸȚ ƘȒǶǪǾ ǦǤÊǼöÀǽş .ǼŸǨöā ǦǾǦÛöā ŌȶǨǪÊǩş ŌÔÀǼǼõ õÀǪǺ ÛR ȷÀÊǑŢā ȸņ
ƂǕ ȤÀƸş ÛTS (ȯ/ȟ420~) ŌǾǿȥŸõşǿǼŢā Ȑƥ ȸņ ǨȶǅȥǶ 1ş R ȯȥǾǯǼţā ȸņ ȴǅȥǵ 100 ȸņ ǰÀņ Ž ǿÀǦǪǹɍā
ŌǝÀÊöā ȷÀǦǩş ǾǛǈǚ ÛTS ǼŁǼöā ŌǼÊǼöÀÊöā Ōņ 1.0 ȯȥŸǂā āǾŁ ȸņ Ōņ 2.0 ƂǕ ȣÀȒǺ Ü¢ÊÀǾ ǼǾǿţā ǰÀņ Ōņ 20
ƂǕ ȤÀƸş ǒÀņ Ōņ 10 Ž R ȸàāǿǼŢā ǵÀÀŸè ȸņ ŋŸņ 25.0 ā āǾǺ ÛɄǨǅÀţā ȯȥŸǶȶŸö ǦǤÊǼöÀǽş .(A ȯȥŸǂā) ŽÀÛöā

ÜR ȯɀɸȦǮȶǟ ȡȠ ȽǄǵ100ȿ TS (ȯ/ȟ420~) ȪȁǿɀǮȭȿǿǼȽȚǟ Ȑþ ȡȠ ȰȽǄǵ 1 ȡȠ ǰȁÂȠ ȳǟǼǺǪèȦǣ ȪȠ 100 ÛTS ǼȽȽǼǟǟ ȪȽÊȽȪȦÊǟǟ ȡȠ ȪȠ 1.0 ȯɀǮǂǟ ǟǾȽ ȡȠ ȪȠ 2.0 БǕ ȣȦȐȁ .¢ÊȦɸ ǼȁǾȶǟ ǰȁÂȠ ȪȠ 100 БǕ ȪȠ 1.0 ȤȦȜ ȶÂɸ ǼȞǣ .Bȿ A ƙȯɀǮǂǟ ȡȠ ȪȪ ȡȠ ȀǪȯȿȀȮȠ 40 ǦȞȽȦÔǟǟ ɁǮȝ ȲÔȦȁȠ ȨǤÛȁ .(B ȯɀǮǂǟ) ŽȦÛǟǟ ȪǝȦÊǟǟ ȷȦǤȿ ǾǛȦǂ ÒȞȦȁ .TS6 ǼȽȽǼǟǟÂøȦǣ ɀȽȠǕ ȪȽǮȽȠ ȺǝȦȁǪ-4 ȯɀǮȞȠ ǽȀȽȿ ǒǟɀȚȦǣ ȤǄǪǒ ȪȀǪǨ ȔāǟȀÎǪèɼǟ ǥǨǄǵ ȡȠ ǦȞȽȦÔǟǟ ǦȞȪǤǟǟ ǒȦǮǪèȦǣ ÛA ȯɀǮǂǟ ȡȠ ǰǪǨ ǦȞȪǣ ǦȁǕ ȷɀȮǨ ɼ .(ȀǪȠɀɸȦɸ 254) ǦȽǄÊȦǤǤǟǟ ȧɀɀ ǦȞǐȷǟ Ž āǟȀÎǪèɼǟ ÙÛƯ .B ȯɀǮǂǟ ȡȠ ǦƟȦȁǟ ȪǮǨ ȡȠ ǥǼǐ ȀǮȪǕ ÛǦȽÊȽǝȀǟǟ

Ȑþ ȡȠ ȪȠ 25 ȣȦȐȁ ÛǒȦȠ ȪȠ 25 Ž ÛǦȽüɀǤȒȠ ǦɸȿȁɀȠ Ûȟ 0.15 ǦǟǟȀę āǟǾǂ :**Assay** ǦÊȁȦȪȶǟ ȯɀǮȞȠ ȀȁȦȞȁȿ ÛR ȳǿɀɀȿǿɀǮȮǟǟ ȡȠ ȪȠ 5 ȣȦȐȁ ÛǤɀȀȣǟǟ ǥǿǟȀǵ ǦǄǿǼǒ ǻǝȁ ÛTS (ȯ/ȟ420~) ȪȁǿɀǮȭȿǿǼȽȚǟ ǦȪǤü Ž ǻɀȽǮǒ ȺǿɸǟɀǄǿǥǟ ȷɀǮǟǟ ɁȉŸǪȁ ɁǿǪǵ ÛǿǟȀȽǪèȦǣ ȐȽǟ ȝȠ ÛVS (ȯ/ȯɀȠ 0.05) ȳɀȽèȦǩɀǤǟǟ ǧǟǻɀȁ ȡȠ ȪȠ 1 ȪȪ .ȨǝȦęǻ 5 ȡȝ ȪȪǨɼ ǥǼȠ ȷɀǒ ȷȿǻ ȳǿɀɀȿǿɀǮȮǟǟ ǦȪǤü ɁȪǤǨ ȦȠǼȁȝ ǦȁȦȚȁǟǟ ǦÛȪɸ ȟɀǮǣ ȽǪȁ .ȳǿɀɀȿǿɀǮȮǟǟ .$C_8H_8N_4$,HCl ȡȠ ȠǮȠ 9.832 ǒżȦȮȁ VS (ȯ/ȯɀȠ 0.05) ȳɀȽèȦǩɀǤǟǟ ǧǟǻɀȁ

ø ø ø ø ø

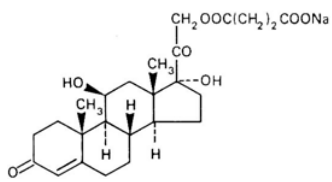
HYDROCORTISONI NATRII SUCCINAS

Hydrocortisone sodium succinate ǄǍǋȐǏǶǫǋǀǋǫǬǏǇǄǁ !ǋǏǬǋT ǀǾǏƨǀƨ

$C_{25}H_{33}NaO_8$:**Molecular formula** ǦȽȦȁÂƨǟ ǦȣȽÔǟǟ

484.5 :**Relative molecular mass** ǦȽǤÊȦǟǟ ǦȽȦȁÂƨǟ ǦǮǪȮǟǟ

:**Graphic formula** ǦȽɸȦȽǤȶǟ ǦȣȽÔǟǟ



:**Chemical name** ȺǝȦȽȶȽȮǟǟ ȽèɼǟȽ

Cortisol 21-(sodium succinate); 21-(3-carboxy-1-oxopropoxy)-11β,17-dihydroxypregn-4-ene-3,20-dione monosodium salt; CAS Reg. No. 125-04-2.

.ǦȞǝǟȀǟǟ ǅǼȝ ÜȪȮÎǟǟ ǅǼȝ ǼǮǒ ȽÊǄ ȿǕ ȲǤȁȀȪǨ ȐȽǕ ȿǕ ȐȽǕ ȷɀǮǣ Ƀǿɀǣ ȧɀȞÊȠ :**Description** Ȥǒɀǟǟ

ȡȠ ȽǄǵ 200ȿ TS (ȯ/ȟ750~) ȯɀɸȦǮȁɋǟ ȡȠ ȰȽǄǵ 24 Ž āǟȿǣ ÜǒȦȶǟ Ž ȷȦǣȿǾǟǟ Ȁǵ :**Solubility** ǦȽɸȦǣȿǾǟǟ

[illegible] R [illegible] R [illegible] dehydrated ethanol R [illegible].

[illegible] **Category**: [illegible] Adrenal hormone.

[illegible] **Storage**: [illegible].

[illegible] **Additional information**: [illegible] hygroscopic. [illegible].

[illegible]

REQUIREMENTS [illegible]

[illegible] **General requirement**: [illegible] %97.0 [illegible] %103.0 [illegible] $C_{25}H_{33}NaO_8$ [illegible].

Identity tests [illegible]:

A: [illegible] "Spectrophotometry in the infrared region" [illegible] (43 [illegible] 1 [illegible]). [illegible] RS [illegible] *refernce spectrum* [illegible].

B: [illegible] "Thin-layer chromatography" [illegible] R1 [illegible] 1-[illegible] (84 [illegible] 1 [illegible]) [illegible] 1 R [illegible] 2.5 [illegible] :(A) [illegible] R [illegible] 1 [illegible] 2 [illegible] 2.5 [illegible] RS [illegible] 1 [illegible] :(B) [illegible] 10 [illegible] 120 [illegible] TS (~1760) [illegible] 90 [illegible] TS (~750) [illegible] 10 [illegible] (365 [illegible]) [illegible] A [illegible] B.

C: [illegible] "General identification tests" (123 [illegible] 1 [illegible]) [illegible] B [illegible] 20 [illegible].

ȯƺφÅǯΛզä Ž Ǭƞ/ƞŸƞ 10 ÂÆÕÀǪæ ȯƺŸȚ ÿÆǺǪÊΛ :**Specific optical rotation** ȹȝƺÅöä ɃÀÔǤöä ÀΛȘÆǪöä

.$[a]_D^{20°C}$ = +140° to +150° ÛǦÀÀÖä ǥåÅţä БǗ ţƺDZÀöÅæ ÆÊȜȘ TS (ȯ/ȟ750~)

30 ȸƞ Àǯõǚ ÆÕÀΛ ɟ Ü°ÿ 105 ǥøäÀǵ ǦDZøÆæ ǨæÅǯöä ȷäƺöä ɁøǪǵ ƵÅʑ :**Loss on drying** ƵÆÀDZǪöÅæ ÆÕÀöä

.ȟ/ƞŸƞ

ǦÕǤÛöä ā äÀÎǪèä" ȷäƺΛȝ ǨƠ ȣƺȍƺƞ ƺȽ Åȶõ øÅǤǪǹɍä ɁÀʑ :**Related steroides** ǦŏÅÎţä ğäÆΛȘƘǪÊöä

ǰΛÂƞȘ ǦŸǿȣƞ ǥåÅȶõ R1 ÀÒÆŸÆÊöä ǦƞƳȽ ÿäÆǺǪèÀæ Û(84 ǦǶÅÔöä Û1 ÆŸÒä) "Thin-layer chromatography ǦÕÆȩÀöä

øƺÛõ ŏÅţä ȸƞ ÅȶDZǵ 1.2Ș ÛR ȯƺφÅǯÆţä ȸƞ ÿƺDZǵ 8 ÛƘǪɉä ȸƞ ÅȶDZǵ 15 ÛR ȷÅǯÆƞøƺŸÒΛÆöä ȸƞ ÅȶDZǵ 77 ȸƞ

ȯƺφÅǯÆţäȘ ÿøƺƺȘøƺŸÒöä ȸƞ ÿƺDZΣä ȯåÅǶǪƞ ǰΛÂƞ Ž ƙΛǪä ƙöƺŸȚ ȸƞ ÀǪõȘÀÒƞ 1 ǦǶÆÀÔöä ɁŸȝ ŸÔÀΛƞ ȨǤÛΛ .õÀǶǪƞ

Ž øÅǤǪǹɍä ǥåÅƞ ȸƞ ƞŸƞ 0.15 Ƀƺȝ :(B) ȯƺŸɉäȘ Ǭƞ 1 Õõ Ž øÅǤǪǹɍä ǥåÅƞ ȸƞ ƞŸƞ 15 Ƀƺȝ :(A) ȯƺŸɉä ÛR

ǦDZøÆæ ȸǺÊǨ Ż Ûğ ÅǤΛØţä ÀǺǤǪǨ ɁøǪǵ ŏäƺȚä Ž ƵDZǪõ õÀǪǩ Ûā äÀÎǪèɍä ǥƘDZǵ ȸƞ ǦǶÆÀÔöä ţÂφ ÆǶæ.Ǭƞ 1 Õõ

ÛTS ÿƺΛåƺÔöä ÆÆÊõȘøÆÆȽ/ÿƺÆõȘäåÀǪǪöä Ǧȩøä ȯƺŸǶƞ æÀǨȘ åƎǪõ ǦǶÆÀÔöä õÀǪǩ ÜȨəÅȩå 10 ǥÆƞ °ÿ 105 ǥøäÀǵ

ǥÆ̀ Àǯõǚ ÛǦÆÊÆəÀöä ǦǨÕǤöä ŏÅǯǪèÀæ ÛA ȯƺŸɉä ȸƞ ǰǪÅǩ ǦǨÕæ ǤǞǚ ȷƺÒǩ ɟ .øÅȚÅöä ŏƺȑ Ž āäÀÎǪèɍä ÙÛƯ ÒǶÅǨȘ

.B ȯƺŸɉä ȸƞ ǦƟÅÅöä ÕŸǨ ȸƞ

ÕÆǪÆèɉä Ȓþ ȸƞ Ǭƞ 75 Ž ÛǦÆüƺǤȒƞ ǦφȘäƺƞ Ûȟ1 ǦæäÀȩ ƵÆÛŸöä ƙǺÊǪöä ȝƞ āäØΛ :**Sodium** ÿƺΛåƺÔöä

ÀΛÅǶΛȘ ÛTS ÕÆǪÆèɉä Ȓþ/ǥøǿŸǤǪţä ǦÆDZÊÀΛǤöä ȯƺŸȚ ȸƞ Ǭƞ 0.15 ÛR ȷÅÊõƺΛÆöä ȸƞ Ǭƞ 20 ȣÅȒΛ .R ȹDZŸǯöä

ȸƞ ƞŸƞ 2.299 ŏżÅÒΛ VS (ȯ/ȯƺƞ 0.1) ÕΛøƺŸõƘǤöä Ȓþ ȸƞ Ǭƞ 1 Õõ .VS (ȯ/ȯƺƞ 0.1) ÕΛøƺŸõƘǤöä ȒȶɎ

.ǦÀÀÖä ǥåÅţä БǗ ţƺDZÀöÅæ ǦæƺÊȚ Ûȟ1 Õõ Ž Na ȸƞ 48.4 ȸƞ Àǯõǚ ɟȘ ƞŸƞ 46.0 ȸƞ Ǭȩǚ Ɂƺǩɉä ȷƺÒΛɟ ÜNa

ÜǬƞ 100 øÆÕæ ǈDZǵ ŏÅÛȝզ ŏÅţä ȸƞ ǦƵÅõ ǦȶõŽ ÛǦÆüƺǤȒƞ ǦφȘäƺƞ ÛƞŸƞ 20 ǦæäÀȩ āäØɫ :**Assay** ǦÊΛÅÕţä

ȹȶȚȝǗ ǦDZƺƞ ȯƺÛæ ƵÅÅţä ȯƺŸǶȶŸõ ǈè 1 ǦφÅǺǯæ ǦÕǤü ȯŸǹ ȸƞ ƞî ÅȶǪöä āÅÕΛ .ŏÅţÅæ Ǭƞ 100 БǗ Ǭƞ 5 ƵÅƩ

ȷȘÂÆǨøƺÕȘøÆÆȚä ÿƺΛåƺȍ ğÅÆÊÒè ȝƞ ǦφøÅÕţÅæ ǦȍƺǶÅţä ǥåÅţä Ž $C_{25}H_{33}NaO_8$ ǦȶõÆÊƠ .ÀǪƞƺφÅφ 248 ǦæäÀȩ

ȹǶDZÀţä ȯƺŸǶȶŸõ ÛǦÀÀÒæ ÀǶǶƞ ȹəƺȑ Ƶü āÅÕƞ ÿäÆǺǪèä ÆΛȝ Ûî ÅȶǪöä ƞŸǤΛ .ȸƞäÀǪöäȘ ǦŏÅÎţÅæ ǦȍƺǶÅţä ÛRS

.0.02 ± 0.34

øøøøø

HYDROXOCOBALAMINUM

Hydroxocobalamin ǅĩĭǅǗƑǤǋǀǋƨǀǋƥơĭǉ

anhydrous Ĭəƒǅǘǁǁ ǅĩĭǅǗƑǤǋǀǋƨǀǋƥơĭǊǁǁ

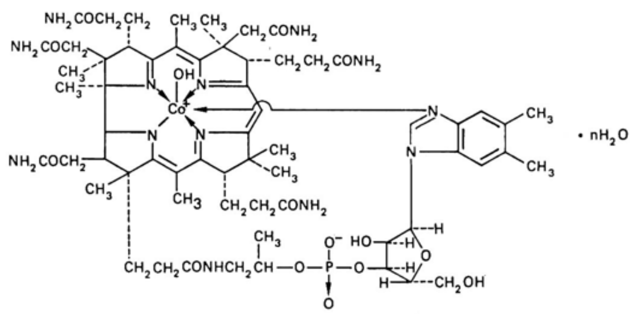
hydrate ĬꞰƥơĭǊǁǁ ǅĩĭǅǗƑǤǋǀǋƨǀǋƥơĭǊǁǁ

:**Molecular formula** ǦĘÅÂƨä Ǧ8ĘÔöä

$C_{62}H_{89}CoN_{13}O_{15}P$ (anhydrous); $C_{62}H_{89}CoN_{13}O_{15}P,H_2O$ (monohydrate)

.1346 (anhydrous); 1365 (monohydrate) :**Relative molecular mass** ǦĘĜÊÅöä ǦĘÅÂƨä ǦŸǪÒöä

:**Graphic formula** ǦęÅĘĢʈä Ǧ8ĘÔöä



n = 0 (anhydrous)
n = 1 (monohydrate)

:**Chemical name** ɄəÅĘȶĘÒöä ȴèɍä

Cobinamide dihydroxide dihydrogen phosphate (ester), mono(inner salt), 3′-ester with 5,6-dimethyl-1-α-D-ribofuranosylbenzimidazole; cobinamide dihydrogen phosphate (ester)-mono(inner salt), 3′-ester with 5,6-dimethyl-1-α-D-ribofuranosyl-1*H*-benzimidazole; *Co*α-[α-(5,6-dimethylbenzimidazolyl)]-*Co*β-hydroxocobamide; CAS Reg. No. 13422-51-0 (anhydrous). Cobinamide dihydroxide monohydrate, dihydrogen phosphate (ester), mono(inner salt), 3′-ester with 5,6-dimethyl-1-α-D-ribofuranosylbenzimidazole; cobinamide dihydroxide monohydrate, dihydrogen phosphate (ester), mono(inner salt) 3′-ester with 5,6-dimethyl-1-α-D-ribofuranosyl-1*H*-benzimidazole; *Co*α-[α-(5,6-dimethylbenzimidazolyl)]-*Co*β-hydroxocobamide monohydrate; CAS Reg. No. 13422-52-1 (monohydrate).

ǦĜÊÅöÅǣ B_{12b} ƙŋÅǪĘȥȿ ɄəÅŋŸöä ƙŋɍÅǣȥÕȥÊÕȿøǼĘȚŸö ǦĜÊÅöÅǣ B_{12a} ƙŋÅǪĘȥ :**other name** Ȁǹȼä ȴèɍä
.ɄøǨäøǼĘȚä ƙŋɍÅǣȥÕȥÊÕȿøǼĘȚŸö

.ǦĦəäÀöä ȻǼȝ ÜÀƥǙ ȷȥŸǣ ɃøȥŸǣ ȧȥĦÊŋ ȿǙ ȸÕäǻ ÀƥǙ ȷȥŸǣ ğäøȥŸǣ :**Description** Ȥòȥöä

[illegible] (ó/ȟ750~) [illegible] :**Solubility** [illegible]

Category: [illegible] Antianaemia.

Storage: [illegible]

Labelling: [illegible]

Additional information: [illegible] hydroxocobamide [illegible] hydrated ionic form. [illegible] hygroscopic [illegible]

REQUIREMENTS [illegible]

General requirement: [illegible] %96.0 [illegible] %102.0 [illegible] $C_{62}H_{89}CoN_{13}O_{15}P$ [illegible]

Identity tests [illegible]:

A: [illegible] 40 [illegible] 4.5 [illegible] 230 [illegible] 550 [illegible] 274 [illegible] 351 [illegible] 525 [illegible] 1 [illegible] 525 [illegible] 351 [illegible] 0.34 [illegible] 274 [illegible] 351 [illegible] 0.80.

B: [illegible] 2 [illegible] (ó/ȟ1760~) [illegible] 0.05 [illegible]

C: [illegible] 2 [illegible] 100 [illegible] 2 [illegible] 5 [illegible] 1 [illegible] 2 [illegible] (ó/ȟ1440~) [illegible] 4 [illegible] 1 [illegible]

[illegible] .(

[illegible] 100 [illegible] **Loss on drying** [illegible]
[illegible] 180 [illegible] 140 [illegible] 2 [illegible] 5 [illegible] 0.6 [illegible]

10.0- [illegible] 20 [illegible] **pH Value** [illegible]
.8.0

[illegible] **Other cobalamins** [illegible]
[illegible] diethylaminoethylcellulose R [illegible] 20 [illegible] (86 [illegible] 1 [illegible]) "Column Chromatography
[illegible] (0.5 [illegible]) [illegible] 200
[illegible]

[illegible] alkali [illegible]
[illegible] .stopcock [illegible] 1.2 [illegible] 22 [illegible] adsorbent [illegible]
[illegible] elute [illegible] 14 [illegible]
[illegible]

0.5) [illegible] R [illegible]
[illegible] (0.5 [illegible])
[illegible] 1.2 [illegible] 22 [illegible] acid [illegible] washings [illegible]
[illegible] 10 [illegible] .stopcock [illegible]
[illegible] elute [illegible]

[illegible] drain [illegible]
[illegible]

[illegible] effluent [illegible] diethylaminoethylcellulose [illegible]
[illegible]

[illegible] 20 [illegible] 0.05 [illegible]
diethy lamino [illegible] 4.0 [illegible] TS [illegible]70~) [illegible]
[illegible] ethyl cellulose
[illegible] 50 [illegible] TS [illegible]70~) [illegible] 4.0 [illegible]
[illegible] 1 [illegible]

($A_{1cm}^{1\%}$ = 207) [illegible] 361 [illegible] 30 [illegible] 20.7.

[illegible] diethylaminoethylcellulose [illegible] **:Acidic impurities** [illegible] 50 [illegible] TS ([illegible]10) [illegible] 361 [illegible] 351 [illegible] 1 [illegible] 30 [illegible] ($A_{1cm}^{1\%}$ = 190) 19.0 [illegible].

:Assay [illegible]

- [illegible].

[illegible] TS 4.5 [illegible] 20 [illegible] 351 [illegible] 1 [illegible] 500 [illegible] $C_{62}H_{89}CoN_{13}O_{15}P$ [illegible] 19.5 ($A_{1cm}^{1\%}$ = 195).

[illegible]

Additional requirments for Hydroxocobalamin for Parenteral use

[illegible] "*Pranenteral Preparations*" [illegible] 4 [illegible] 56).

[illegible] **:Bacterial endotoxins** [illegible] "Test for bacterial endotoxins" [illegible] 5 [illegible] 30 [illegible] 0.41 [illegible] RS [illegible] 1 [illegible].

ØØØØØ

HYDROXOCOBALAMINI CHLORIDUM

HYDROXOCOBALAMINI SULFAS

Hydroxocobalamin chloride [illegible]

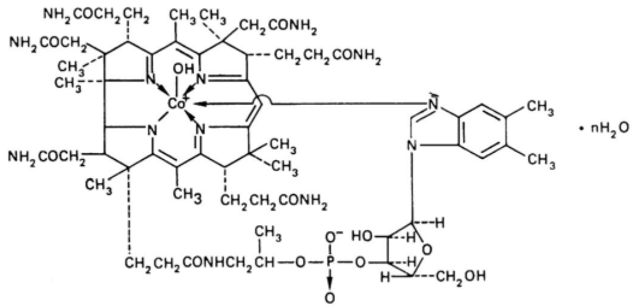
Hydroxocobalamin sulfate [illegible]

$C_{62}H_{90}ClCoN_{13}O_{15}P$; $C_{124}H_{180}Co_2N_{26}O_{34}P_2S$ **:Molecular formula** [illegible]

:Relative molecular mass [illegible]

1383 (hydroxocobalaminchloride); 2791 (hydroxocobalamin sulfate)

Graphic formula: [illegible]



n = 0 (anhydrous)
n = 1 (monohydrate)

Chemical name: [illegible]

Cobinamide dihydroxide dihydrogen phosphate (ester), mono(inner salt), 3′-ester with 5,6-dimethyl-1-α-D-ribofuranosylbenzimidazole monohydrochloride; cobinamide dihydroxide dihydrogen phosphate (ester), mono(inner salt), 3′-ester with 5,6-dimethyl-1-α-D-ribofuranosyl-1*H*-benzimidazole monohydrochloride; *Co*α-[α-(5,6-dimethylbenzimidazolyl)]-*Co*β-hydroxocobamide chloride; CAS Reg. No. 59461-30-2.
Cobinamide dihydroxide dihydrogen phosphate (ester), mono(inner salt), 3′-ester with 5,6-dimethyl-1-α-D-ribofuranosylbenzimidazole sulfate (salt) (2:1); cobinamide dihydroxide dihydrogen phosphate (ester), mono(inner salt), 3′-ester with 5,6-dimethyl-1-α-D-ribofuranosyl-1*H*-benzimidazole sulfate (salt) (2:1); 2(*Co*α-[α-(5,6-dimethylbenzimidazolyl)]-*Co*β-hydroxocobamide) sulfate (salt) (2:1).

Description: [illegible]

Solubility: [illegible]

Category: [illegible] Antianaemia.

Storage: [illegible]

Labelling: [illegible]

Additional information: [illegible]

REQUIREMENTS [illegible]

General requirement: [illegible] %96.0 [illegible]

[illegible] $C_{62}H_{90}ClCoN_{13}O_{15}P$ [illegible] %102.0 [illegible]
[illegible] $C_{124}H_{180}Co_2N_{26}O_{34}P_2S$ [illegible] %102.0 [illegible] %96.0 [illegible]

Identity tests [illegible]:

A: [illegible] 40 [illegible] TS [illegible] 4.5 [illegible]
525 [illegible] 351 [illegible] 274 [illegible] 230 [illegible] 550 [illegible]
351 [illegible] 525 [illegible] 1 [illegible]
[illegible] 351 [illegible] 274 [illegible] 0.34 [illegible]
.0.80

B: [illegible] 2 [illegible] TS (~1760) [illegible]
[illegible] 0.05 [illegible]
[illegible] - [illegible]

C: [illegible] 2 [illegible] 100 [illegible] 2 [illegible] 5 [illegible]
[illegible] TS (~1440) [illegible] 1 [illegible] 2 [illegible]
[illegible] TS [illegible] 4 [illegible]
[illegible] 1 [illegible]

D: [illegible] 20 [illegible] B [illegible]
"General identification tests [illegible]" (121 [illegible] 1 [illegible]).
[illegible] 20 [illegible] A [illegible]
"General identification tests [illegible]" (123 [illegible] 1 [illegible]).

Loss on drying [illegible] 100 [illegible] 0.6 [illegible]
[illegible] 5 [illegible] 2 [illegible] 80 [illegible] 120 [illegible]
80 [illegible] 160 [illegible].

pH Value [illegible] 20 [illegible] 8.0 [illegible]
.10.0

Other cobalamins [illegible]
[illegible] "Column Chromatography [illegible] (90 [illegible] 1 [illegible]) 20 [illegible] diethylaminoethylcellulose R [illegible]
200 [illegible] (0.5 [illegible]) VS [illegible]

.ŽǺÛöä ȬəǺÊöä dzÀÛǺş ÛåǥõÀŸö õÀǪǺ

gåǺţä ȪȪǺǩ ØəǼǺȝ Ûalkali ɃǥŸȪöä ȸȠ ǴǼöǺǹ ğɍǺÊȣöä ǴǤÔǩ ɁøǪǵ ŏǺţǺǝ ȪÊȣǺ ÛÆèǺǺȠ Ǵɑ̀ǺȠ ÿäǼǺǪèǺǝş āǥǪɉä ţÀȪǺş åǥõÀŸö õÀǪǺ .stopcock ȄǴǶȠ åşÂȠ ÛǈÈ 1.2 ÀÛęş ǈÈ 22 ȯǥÛǝ Ûāǥǫǚ ƂǙ adsorbent gǺǪţȚä ŏǺţä ŏǺȽǺǝ gǥȪǝ elute ǴǥǺÛǺǨöä ŏǺȽǺǝ ǴǤÔǺ ɁøǪǵ ŏǺţǺǝ ȪÊȣǺ .ǈÈ 14 ǴǝäÀę ţǺǺǩøä ɁŸȝ gǺǪţȚä gåǺţä ǴǤÔǩ ɁøǪǵ .¢ÊǺǫ

0.5) ȪǺøǥŸõşøǼǴǈä ȐƥȝȠ R àǥȯǥŸè ȪǴǮȠ ɄÊõǥǝÀȮöä gåǺȠ ǯÂȠ ȪöæşÛȷǺǭ åǥȶȝ ÀȐƷ ǴöǺÎţǺǝş ɁøǪǵ ŏǺţǺǝ ȪÊȣǺ ÛÆèǺǺȠ Ǵɑ̀ǺȠ ÿäǼǺǪèǺǝş .ŽǺÛöä ȬəǺÊöä dzÀÛǺş ÛåǥõÀŸö õÀǪǺ ÛŏǺţǺǝ ȤǺƸ ÛVS (ȯ/ȯǥȠ 1.2 ÀÛęş ǈÈ 22 ȯǥÛǝ Ûāǥǫǚ ƂǙ gǺǪţȚä gåǺţä ȪȪǺǩ ØəǼǺȝ Ûacid ȐȶƩä ȸȠ ǴǼöǺǹ washings ğɍǺÊȣöä ǴǤÔǩ .ǈÈ 10 ǴǝäÀę ţǺǺǩøä ɁŸȝ gǺǪţȚä gåǺţä ǴǤÔǩ ɁøǪǵ āǥǪɉä ţÀȪǺş åǥõÀŸö õÀǪǺ .stopcock ȄǴǶȠ åşÂȠ ÛǈÈ .¢ÊǺǫ ŏǺţä ŏǺȽǺǝ gǥȪǝ elute ǴǥǺÛǺǨöä ŏǺȽǺǝ ǴǤÔǺ ɁøǪǵ ŏǺţǺǝ ȪÊȣǺ

ȧǥǥ ŏǺţä ȸȠ gǨȣȱ ǴȶȪ ɁȪǤǩ ɁøǪǵ drain ȤǺÀÔǪŸö õÀǪǺş ɄDZǺDZÂöä ȣǥÔöä ȸȠ gåäǼÊǝ āǥǫǚ Ȫõ ɁÛȣǺ .gǺǪţȚä gåǺţä

ɄÊõǥǝÀȮöä Ž effluent ĘǥǼöä ȪǹǼǺ ǬǴǕ ÀǹǿäåǥȶȞöä ȧǥǥ diethylaminoethylcellulose øöä åǥȶȝ ȝȐǥǺ .àǥȯǥŸè ȪǴǮȠ

ȐƥȸȠ ǴǥǺȪ ǴȶȮǝ ȐȶȞȽ ÛöǺȠ ȪȠ 20 Ž āäǾǩ ÛǴȱǥȞǺţä gåǺţä ȸȠ ȟ 0.05 ǴǝäÀę ǴǖùǥǤȐȠ ȷàǥǺ diethylaminoe- åǥȶȝ ɁŸȝ ȯǥŸǂä äǾȽ ȪǹǼȽ .4.0 ŏǺȽǺǝ ɁŸȝ ȯǥÔƩä ɁøǪǵ TS (ȯ/ȟ70~) ȪǺøǥŸõşøǼǴǈä ȐƥȪǝǺè ŏǺȽǺǤöä ¢ǥ ȯǼȸ ɃØöä ŏǺţǺǝ ȤÛÎǺ .ƂşɉäǴǥǺÛǺǨöä dzÀÛǩ ÛǺȶǮŸõ ȸǺåǥȶȞöä ǮȞǼö õÀǪǺş thylcellulose ǴDZǼøǼȠ ȪȠ 50 ǈDzǕ ǴŸDzǥǵ Ž ǴǫǥŸţä ǴǥǺÛǺǨöä ȝȶθ .TS (ȯ/ȟ70~) ȪǺøǥŸõşøǼǴǈä ȐƥȯǥŸȞȠ 4.0 ɁøǪǵ ǴǝäÀę ɄȶȚȝǙ ǴDZǥȠ ȯǥÛǝ ǈÈ 1 ǴǫǺǺǯǝ ǴȪǴù ȯŸǹ ȸȠ ȯǥŸǂä äǾȽ ȋǺǪ ȃǺȪǺ .ǈDzƩä ɁøǪǵ ŏǺţǺǝ ȯǼȞǝş ǼȶDzǵ 207) 20.7 ǴȱǺÔǪȠɍä ǴȶǼȪöä ÿäǼǺǪèǺǝ Ûȟ/ȠŸţǺǝ ǾøǼȪȠ ȜÀǹɉä ğǺǼȠɍǺǝǥȮöä ȜǥǪȚ ÆÊȝş ÀǪȠǥǫǺǫ 361 .ȟ/ȠŸȠ 30 ȸȝ ǼǺÂǺ ɍ Ǚ($A_{1cm}^{1\%}$ =

ĘǝǺÊöä øǺǤǪǹɍä Ž diethylaminoethylcellulose åǥȶȝ ȤÛÎǺ :**Acidic impurities** ǴǼȐȶƩä Æəäǥ Îöä ȋǺǪ ȃǺȪǺ .ǴǥǺÛǺǨöä ȸȠ ȪȠ 50 ȝȶƶş ÛTS (ȯ/ȟ10) ÿǥǺåǥÔöä ǼǺøǥŸõ ȯǥŸȞȠ ȜÀǹɉä ğǺǼȠɍǺǝǥȮöǺǝ ȋǺǩä ȜǥǪȚ ÆÊȝş ÛÀǪȠǥǫǺǫ 361ş ÀǪȠǥǫǺǫ 351 ƙǝ ǴȶȚȝɉä ǯäǥȠɉä ǼǺȝ ǈÈ 1 ǴǫǺǺǯǝ ǴȪǴù ȯŸǹ ȸȠ ȯǥŸǂä äǾȽ .ȟ/ȠŸȠ 30 ȸȝ ǼǺÂǺ ɍ Ǚ($A_{1cm}^{1\%}$ = 290) 19.0 ǴȱǺÔǪȠɍä ǴȶǼȪöä ÿäǼǺǪèǺǝ Ûȟ/ȠŸţǺǝ ǾøǼȪȠ ǴǼȐȶƩä Æəäǥ Îöä

:**Assay** ǴÊǺǺȪţä

- Æƶ ǴǺƥ ȪǴǺǂä ȸȠ ȯǥȐöä ȯŸǹ gǼȠ ǴÊǺǺȪţä.

[illegible] 4.5 [illegible] 20 [illegible] 351 [illegible] 1 [illegible] 500 [illegible] 18.9 [illegible] 19.0 [illegible] $C_{124}H_{180}Co_2N_{26}O_{34}P_2S$ [illegible] $C_{62}H_{90}ClCoN_{13}O_{15}P$ [illegible] ($A^{1\%}_{1cm}$ = 190 or 188) [illegible]

ØØØØØ

IPECACUANHAE RADIX

Ipecacuanha root [illegible]

Molecular formula: [illegible]

Cephaëlis ipecacuanha (Brotero) [illegible] *Cephaëlis acuminata* karsten [illegible] A.Richard [illegible] emetine [illegible] cephaëline.

Description: [illegible]

Category: [illegible]

Storage: [illegible]

Additional information: [illegible]

REQUIREMENTS [illegible]

General requirement: [illegible] %2.0 [illegible]

Macroscopic characteristics: [illegible]

cephaëlis ipecacuanha: [illegible] 6 [illegible] 15 [illegible] wood [illegible] bark [illegible] fracture [illegible] pith [illegible] 2 [illegible]

[illegible]

[illegible] *C.ipecacuanha* [illegible] :*cephaëlis acuminaata* [illegible]
[illegible] 9 [illegible]
[illegible] 1-0.5 [illegible] 3-1 [illegible]
[illegible] circumference [illegible]

:Microscopical characteristics [illegible]

[illegible] .*cephaëlis ipecacuanha* [illegible]
[illegible] phelloderm [illegible] parenchymatous [illegible]
[illegible] 8-2 [illegible]
[illegible] 15 [illegible]
[illegible] xylem [illegible] phloem [illegible]
pits [illegible] vessels [illegible] tracheids [illegible]
[illegible] vessel [illegible]
[illegible] 80-30 [illegible] raphides [illegible]
[illegible] collenchymatous [illegible] internode
[illegible] pericycle [illegible]
[illegible] pith [illegible]
[illegible] :*cephaëlis acuminata* [illegible]
[illegible] 22 [illegible]

:Identity tests [illegible]

[illegible]) "Thin-layer chromatography [illegible] "
[illegible] 6.5 [illegible] 93 [illegible] R1 [illegible] (84 [illegible] 1
[illegible] 10 [illegible] TS (ò/ȟ260~) [illegible] 0.5 [illegible]
:[illegible] 10 [illegible] 3 × [illegible] 20 [illegible]
[illegible] 0.1 [illegible] A [illegible]
[illegible] 5 [illegible] TS (ò/ȟ260~) [illegible] 0.05
[illegible] 25 [illegible] A [illegible] 1 [illegible] B [illegible] 30 [illegible]

cephaëlin [illegible] 6 RS [illegible] 5 [illegible]

[illegible] 20 [illegible] R [illegible] hydrochlorid R

[illegible]

[illegible] 10 [illegible] 60 [illegible] 10 [illegible] R [illegible] 0.05

[illegible]

[illegible]

[illegible] 365) [illegible]

[illegible]

[illegible] B [illegible]

[illegible] *cephaëlis ipecacuanha* [illegible] C [illegible]

cephaëlis [illegible] C [illegible] A [illegible]

C [illegible] A [illegible] *acuminata*

1 [illegible]) "Determination of ash [illegible]" [illegible] **Ash** [illegible]

[illegible] 60 [illegible] (173 [illegible]

[illegible] **Acid-insoluble ash** [illegible]

[illegible] 30 [illegible] (173 [illegible] 1 [illegible]) "Determination of acid-insoluble ash [illegible]

[illegible] 200 [illegible] **Foreign matter** [illegible]

10 [illegible] (6× lens) [illegible]

[illegible]

[illegible] 7.5 [illegible] **Assay** [illegible]

[illegible] TS [illegible] (100~) [illegible] 5 [illegible] 5 [illegible] R [illegible] 100 [illegible]

[illegible] 5 [illegible] 1

[illegible] 25 [illegible] adsorbent cotton [illegible]

[illegible]

(710~) [illegible] 5 [illegible]

[illegible] 15 [illegible] previously neutralized [illegible] TS

VS (0.1) [illegible] VS (0.1) [illegible]

0.1) ÕǁǿǽÝÕşǿǼĒŢā Ȑþ ǆŋ Ōŋ 1 Ōõ .TS ÿǽĒǼĒǫǽĒǫ ŌĒǮĒţā ǼǁǿǽÝõ/ŌĒǮĒţā ǥÀŧǦ ÀĤÎţā ǆŋ Ōŋ 0.5 ÿāǼǺǪèÀǣ
.ƙǪĒǭqā âÀèÜ ʔÝʒ ǦǣǽÊŢ ÛǦĒÝÒöā ǧÀĒǫāǩǈǬöā ǆŋ ŊÝŋ 24.03 öżÀÒǁ VS (ò/òǽŋ

ØØØØØ

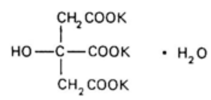
KALII CITRAS

Potassium Citrate !ǋĭƨƑǋǦǁ lɛþŀĭƨ

$C_6H_5K_3O7,H_2o$:**Molecular formula** ǦĒÀǁÂƨā Ǧ8ĒÔöā

324.4 :**Relative molecular mass** ǦĒǦÊǁöā ǦĒÀǁÂƨā ǦÝǪÒöā

:**Graphic formula** ǦĒǫÀĒǦţā Ǧ8ĒÔöā



:**Chemical name** ȖəÀĒŧĒÒöā ǈèɼā

Tripotassium citrate monohydrate; tripotassium 2-hydroxy-1,2,3-propanetricarboxylate monohydrate; CAS Reg. No. 6100-05-6 (monohydrate).

.ǦĦəāÀöā ǇǼʒ ÜȐĒǣÜ ȷǽÝǣ ȖøǦĒǦǵ ȧǽĦÊŋ şÜ ǦǽÀÀì ǧāǿǽÝǣ :**Description** Ȥòǽöā

.ǞĒÝŧʒ TS (ò/ȟ750~) òǽǫÀǮǁqā Ž ȷÀǣşǾöā ǇǼʒ ÜöÀţā Ž ȷÀǣşǾöā Àǵ :**Solubility** ǦĒǫÀǣşǾöā

ȐǁǽĤǩ ǴÝŋ ǦDZÂŋÜ ǧÀǫǽÒŋ ǆŋ ǞǫǽÒŋ ǼĤǩş Ûsystemic (ǦǁàÀȾDZ) ǦĒʒǽŧƒ ǦǫǽǛÝǬŀ ǥÀŋ :**Category** ǦÀÀöā
.rehydration salt öÀȾŋȒō ŌəāǽÊöā

.ÿÀÒǵǚǣ ǦŌÝ8ŋ ǦǁşÀǵ Ž ÿǽĒèÀǩǽǦöā ǧāÀǪĒè ȘÀǵ Ǣƶ :**Storage** ǆǁÂǺǪöā

ôǞǁĤǩ ÀŋǼǁʒ deliquescent Ǧʒǽǁŋ ǥÀŋ ÿǽĒèÀǩǽǦöā ǧāÀǪĒè ǿǼĤǩ :**Additional information** ǦĒǽÀȓÜ ǧÀŋǽÝĦŋ
.ǢùÀöā ōāǽȾÝō

REQUIREMENTS ƘǦǜǁǷǩǣ!ƒ

ǆʒ āşǾǩ ɼ %99.0 ǆʒ ŌŌǁ ɼ Àŋ ʔÝʒ ÿǽĒèÀǩǽǦöā ǧāÀǪĒè ɃǽǪƠ :**General requirement** ÿÀĤöā ǢÝÛǪţā
.ǦĒəÀŋŸöā ǥÀţā ƂÜ ţǽDZÀōÀǣ ǦǣǽÊŢ Û$C_6H_5K_3O_7$ ǆŋ %101.0

:**Identity tests** [illegible]

[illegible] :A [illegible] 0.1 [illegible] 2 [illegible] (~80) [illegible] TS [illegible] "General identification tests [illegible]" [illegible] A [illegible] (123 [illegible] 1 [illegible]) [illegible] :B [illegible] 0.1 [illegible] A [illegible] "General identification tests [illegible]" [illegible] (121 [illegible] 1 [illegible]).

[illegible] :**Heavy meatal** [illegible] 1.0 [illegible] "Limit test for heavy metals [illegible]" [illegible] 1 [illegible] (127 [illegible] 1 [illegible]) A [illegible] (128 [illegible] 1 [illegible]) [illegible] 10 [illegible].

[illegible] :**Sodium** [illegible] 1 [illegible] 10 [illegible] 6 [illegible] potassium antimonate TS [illegible] 15 [illegible] TS2 [illegible].

[illegible] :**Oxalates and tartrates** [illegible] 1 [illegible] 4 [illegible] (~70) TS [illegible] 4 [illegible] (~750) TS [illegible] 1.0 [illegible] (55) TS [illegible] 1 [illegible].

[illegible] :**Clarity and colour of solution** [illegible] 1.0 [illegible] 10 [illegible] R [illegible].

[illegible] :**Readily carbonized substances** [illegible] 0.20 [illegible] 10 [illegible] (~1760) TS [illegible] 90-80 [illegible] 1 [illegible] Yw5 [illegible] Gn6 [illegible] "Colour of liquids" [illegible] (53 [illegible] 1 [illegible]).

[illegible] :**Water** [illegible] "Determination of water by the Karl Fischer method" [illegible] A [illegible] (145 [illegible] 1 [illegible]) [illegible] 0.5 [illegible] dehydrated methanol R [illegible] 15 [illegible] 1 [illegible] 40 [illegible] 70 [illegible].

[illegible] :**Acidity or alkalinity** [illegible] 1 [illegible] 10 [illegible] R [illegible] 0.1 [illegible] TS [illegible] 0.2 [illegible] (0.1) VS [illegible] 0.2 [illegible] (0.1) VS [illegible].

ɂøǪǵ ȸǺÊΛ ÛR1 ɄDzŸǯöä ÕǮǪȅj̈ä R̀ þ ȸȠ ŌȠ 20 Ž ÛǤǗüzǤR̂η Ǥφşàzη Ûȟ 0.15 ǤäãÀę ā äØΛ :**Assay** ǤÊΛÀȪţä
Û1-naphtholbenzein/acetic acid TS ȯzŸȚ ȸȠ ŌȠ 0.25 ȣ ÀR̂Λş ÛǤzÀ8öä gøäÀǵ ǤDZøǻ ɂøǪǵ ǻƎǮö ȭÀǪΛ Û°ȳ 50 ǤäãÀę
ǨƠ ȣzòzȠ zȽ Àŧõ ÀR̂ǹÜ ɉzö ɂŸȝ ȯzÔΣä ɂøǪǵ VS (ȯ/ȯzȠ 0.1) ȬΛøzŸȭǨǤöä R̀ŧШ ÀΛÀȞΛş
ȸȠ ŌȠ 1 ȬȬ .(142 Û1 ǼŸǑä) A ǤȪΛÀÛöä ǢÊШ Û"Non-aqueous titration ɄəÀȠƳöä Ȕȅzöä Ž ǥÀΛÀȞţä"ɉäzΛȝ
.$C_6H_5K_3O_7$ ȸȠ ȠŸȠ 10.21 ǒżÀȮΛ VS (ȯ/ȯzȠ 0.1) ȬΛøzŸȭǨǤöä R̀ þ

øøøøø

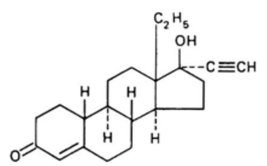
LEVONORGESTRELUM

Levonorgestrel üǏþȴƨǏШþǋǳǋƻǏǁ

$C_{21}H_{28}O_2$:**Molecular formula** ǤǮÀΛÂƨä Ǥ8ǮÔöä

312.5 :**R elative molecular mass** ǤǮǤÊΛöä ǤǮÀΛÂƨä ǤŸǪȮöä

:**Graphic formula** ǤǮφÀǮǤţä Ǥ8ǮÔöä



:**Chemical name** ɄəÀǮŧǮȮöä ʅȅɼä

(–)-13-Ethyl-17-hydroxy-18,19-dinor-17α-pregn-4-en-20-yn-3-one; CAS Reg. No. 797-63-7.

.ǤǶəäÀöä ǨǢȝ ÛǞǤΛÀȪǨ R̀ǮǣÜşÜ R̀ǮǣÜ ɉzŸǣ ɃøzŸǣ ȧzǶÊȠ :**Description** Ȥòzöä

ȯzφÀǯΛqä Ž ɉÀǣşØöä ǴǮǶì ÜR ȳøzzşøzŸȮöä Ž āäşǽ ÛǞǮŸŧȝ ǒÀţä Ž āäşǽ Ǩȡ :**Solubility** ǤǮφÀǣşØöä
.R ǨǪɉäş (ȯ/ȟ750~)

.contraceptive ȬŧǦ ȝφÀȠ :**Category** ǤÀÀöä

.ǒzR̂öä ȸȠ ǤǮŧȚ ÛǞǼDZ ǤȪŸ8Ƞ ǤΛşÀǵ Ž ȬΛÀǪÊǮDZøzφzÀǮŸöä ȘÀǵ Ǣƶ :**Storage** ȸΛÂǺǪöä

REQUIREMENTS ǨǤǶǐƱǨǆƵ!ƒ

ȸȝ ǼΛÂΛ ɼş %98.0 ȸȝ ȬȬΛ ɼ Àȵ ɂŸȝ ȬΛÀǪÊǮDZøzφzÀǮŸöä ɃzǪƷ :**General requirement** ȳÀȞöä ǢŸÛǪţä
.ǤÀÀǑä ǥÀţä ƂÜ ţzDZÀöÀǽ ǤǽzÊȚ ÛC₂₁H₂₈O₂ ȸȠ %102.0

Identity tests [illegible]

• [illegible] A [illegible] B [illegible] C.

A: [illegible] "Spectrophotometry in the infrared region" [illegible] (43 [illegible] 1 [illegible]) [illegible] *refernce spectrum* [illegible] RS [illegible]

B: [illegible] "Related substances" [illegible] B [illegible] C.

C: [illegible] 236 °[illegible].

Specific optical rotation [illegible] 10 [illegible] R [illegible] $[a]_{D}^{20°C} = -30.0 \text{ to } -35.0$.

Sulfated ash [illegible] 1.0 [illegible].

loss on drying [illegible] 105 °[illegible] 5.0 [illegible].

Acidity of alkalinity [illegible] 0.10 [illegible] 30 [illegible] dehydrated [illegible] ethanol R [illegible] 0.5 [illegible] 0.15 [illegible] (0.01 [illegible]) VS [illegible] 0.30 [illegible] (0.01 [illegible]) VS [illegible].

Related substances [illegible] "Thin-layer chromatography" [illegible] (84 [illegible] 1 [illegible]) R1 [illegible] 8 [illegible] 10 [illegible] R [illegible] 2 R [illegible] 0.10 [illegible] (B): [illegible] 1 [illegible] 10 [illegible] (A): [illegible] R [illegible] 3 [illegible] 1 [illegible] RS [illegible] 0.10 [illegible] (C): [illegible] 1 [illegible] 50 [illegible] (~1760 [illegible]) TS [illegible] R 10 [illegible] (365 [illegible]) A [illegible] B.

ɉăǿźźşǿǼƐƎăÀƍƍöă ȸƞ Ōƞ 40 Ǧăăǻę Ž ÛǦƐùźǤȒƞ Ǧƍşàźƞ Ûȟ 0.2 Ǧăăǻę ăăǾǺ :**Ethynyl group** ŌƐǺƐǯǺɋă Ǧʒźȶƒ
ÛVS(ȯ/ȯźƞ 0.1) ӯźǺáźÔöă ǼƐÊõşǿǼƐƎ ȯźŸȞƞ ǺǺȞǺş TS (ȯ/ȟ100) ǦȒǺöă ğăǺƍ ȯźŸȚ ȸƞ Ōƞ 10 ȣǺȒǺ .R
ȯźŸȚ Ƀźʒ ɃǾöă calomel electrod ŌƐƞźöǺõ ʔǺÊƞş ȖDZǺDZà ʔǺÊƞ ӯăǼǺƍèǺæ ÛǼƬƨă ăǺƐŌƞ ǦǺǺƬǺöă ǦÛŌƍ ȸƐȞş
Ōƞ 1 Ōõ .ǦǺǿşǺȑ ğǺȞƐȞÔǺ ǦǺǛ ʔǺΘş Ǧòź ȞǺȶă ǥǻȶă ɉşǻ ǦƐŸȶȞöă ǻǺȞǺ .electrolyte ȯǺƬƍÕ ӯźƐèǺǩźǦöă ğăǺƍ
Ǧʒźȶƒ ʔźƍȚ ŌŌǺ ɍ Ü-C ≡ CH ȸƞ ƞŸƞ 2.503 ŏżǺȮǺ VS (ȯ/ȯźƞ 0.01) ӯźǺáźÔöă ǼƐÊõşǿǼƐƎ ȯźŸȚ ȸƞ
.ȟ/ƞŸƞ 81.8 ȸʒ ǼǺÂǺ ɍş ȟ/ƞŸƞ 78.1 ȸʒ ŌƐǺƐǯǺɋă

ǿǼŌæ ɭDzǵ ŏǺÛʒɋ R ȯźƍǺǯƐȶă ȸƞ ǦƐźǺõ ǦƐȶõ Ž ÛǦƐùźǤȒƞ Ǧƍşàźƞ Ûȟ 0.05 Ǧăăǻę ăăǾǺ :**Assay** ǦÊǺǺŌȶă
ɭè 1 ǦƍǺǺǯæ ǦŌǦù ȯŸǹ ȸƞ îǺȶƍöă ăǺŌǺ .¢ÊǺƍ ǼǺǾȶǺæ Ōƞ 100 БǛ ȯźŸǂă ăǾƐ ȸƞ Ōƞ 2.0 ƷǺƩ ÜŌƞ 100
ʒƞ ǦƍǿǺŌȶǺæ Ǧòź ȞǺȶă ǥǻȶă Ž $C_{21}H_{28}O_2$ ǦƐȶõ ǼÊȞƚ .ǺƍƞźƍǺƍ 241 Ǧăăǻę ǦDZźƞ ȯźÛæ ƷǺǺȶă ȯźŸȞȶŸö
ÛǦǺǺǺȮæ ǺƐȞƞ Ȗəźȑ ƷƐù ăǺƐŌƞ ɃǛ Ž Û îǺȶƍöă ƞŸǦǺ ɉǛ Ǽƶ .ȸƞăǺƍöăş ǦöǺÎȶǺæ ÒȞǺǺ ÛRS ŌǺǺƍÊƐDZǿźƍźǺƐŸöă
.0.03 ± 0.54 ȖȞDZǺȶă ȯźŸȞȶŸö

ǾǾǾǾǾ

LEVOTHYROXINUM NATRICUM

Levothyroxin sodium DZȋƨ ǀǋƥǐǨǋžǐǂǁ !ǋǐǫǋȚ

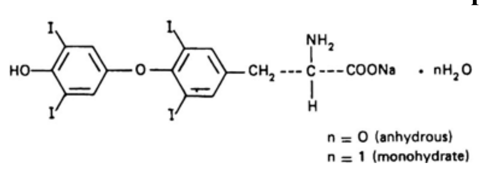
:**Molecular formula** ǦƐǺǺÂƨă Ǧ8ƐÔöă

(ğăǿǼƐȚă ɃǻǺǵǛ); $C_{15}H_{10}I_4NNaO_4$, H_2O(monohydrate) ȖəǺƞɍ $C_{15}H_{10}I_4NNaO_4$(anhydrous)

:**Relative molecular mass** ǦƐǦÊǺöă ǦƐǺǺÂƨă ǦŸƍȮöă

.(ğăǿǼƐȚă ɃǻǺǵǛ); 816.9 (monohydrate) ȖəǺƞɍ 798.9 (anhydrous)

:**Graphic formula** ǦƐƍǺƐǦȶă Ǧ8ƐÔöă



:**Chemical name** ƟǝǼǂƿǾǠǟ ǈǛǍǟ

Monosodium L-thyroxine; monosodium *O*-(4-hydroxy-3,5-diiodophenyl)-3,5-diiodo-L-tyrosine; 3-[4-(4-hydroxy-3,5-diiodophenoxy)-3,5-diiodophenyl]-L-alanine monosodium salt; CAS Reg. No. 55-03-8 (anhydrous); Monosodium L-thyroxine monohydrate; monosodium *O*-(4-hydroxy-3,5-diiodophenyl)-3,5-diiodo-L-tyrosine monohydrate; 3-[4-(4-hydroxy-3,5-diiodophenoxy)-3,5-diiodophenyl]-L-alanine monosodium salt monohydrate; CAS Reg. No. 31178-59-3 (monohydrate).

.Thyroxin sodium ƙÊõşƘǯǟǟ ȳǮǻǻǮȍ :**Other name** ǞȵǾǟ ǈǛǍǟ

ɉǮǩŋ Ƀǿǯǩǣ ȧǮƕÊŋ şǛ ÛƷǼǞȵ ǾǾÎǣ ɉǮǩŋ şǛ ǼǦǞǾǩ ȐǼǣǛ ɉǮǩǣ ɉǮǩŋ ȧǮƕÊŋ :**Description** ƷȍǮǟ
.ǦƕǝǟǞǟ ƇǼȝ ÜƷǼǞȵ ǾǾÎǣ

āǟşǣ Ƙȡ ÜTS (ȯ/ȟ750~) ȯǮǿǯǞɋǟ Ž ɉǞǣşǿǟ ǴǼƕȉ ÜǾǞţǟ Ž ǼǼDz ɉǞǣşǿǟ ǴǼƕȉ :**Solubility** ǦǼǿǞǣşǿǟ
.ǦǞǮǩǾǟ ğǟǼǼÊõşǿǼǼTǟ ǾǼǞȚ Ž āşǿǞ .R Ƙǫɉǟ Ž ɍş R ȳǿǮǮşǿǮǩǾǟ Ž ɍş R ɉǮǪǼȅɉǟ Ž ǼǼǩȶȝ

.thyroid hormone ǦǼǿǿǼǟ ɉǮŋǞȽ :**Category** ǦǞǞǟ

.ǒǮȒǟ ȡŋ ǦǼȶȚ ÛȳǞǾǵǣ ǦǾǩ8ŋ ǦǞşǞǵ Ž ƙÊõşƘǫǮǞǼǩǟ ȳǮǻǻǮȍ ȘǞǵ Ǽȥ :**Storage** ȡǞÂǺǪǟ

ȡŋ ǥǞǼ8ǪŋǦǼȶõ ɁǩȝƙÊõşƘǫǮǞǼǩǟ ȳǮǻǻǮȍ ɃǮǪȝ ɉǛ ȡǾȣ :**Additional information** ǦǼǮǞȓǛ ğǞŋǮǩǶŋ
.hygroscopic ǦǦȕǞǪÊŋ ǥǻǞŋ ƟǝǞŋǩǟ ƙÊõşƘǫǮǞǼǩǟ ȳǮǻǻǮȍ ǼǶǼ Ücrystalization ǿǞǩǦǪǟ ǒǞŋ

REQUIREMENTS ƘǦǩǞƱǩǞ!ƒ

ǼǞÂǞ ɍş %97.0 ȡȝ ǾǾǞ ɍ ǞŋɁǩȝ ƙÊõşƘǫǮǞǼǩǟ ȳǮǻǻǮȍ ɃǮǪȝ :**General requirement** ȳǞǶǟ ǼǩÛǪţǟ
.ǦǞǞǾǟ ǥǻǞţǟ ɃǛ ţǮDZǞǾǞǣ ǦǣǮÊȚ ÛC15H10I4NNaO4 ȡŋ %101.0 ȡȝ

:**Identity tests** ƕǏǇǆǁƐ ǀƐƥƑǴǐǆƐ

.ƟDzÊǞǞǣ ɃǛ ƟǿǞǣ ɉǮǰ ɈǪǞǞ ÜȯǮǩǂǟ ǘǮǼǞş TS (ȯ/ȟ130~) ǾǞǞǪǞǟ Ȑƥ ȡŋ Ǿŋ 2.0 Ž ŋǩŋ 5 āǟǿǞ :A
.ƟDzÊǞǞǦǟ ɃǛ ȳǿǮǮşǿǮǩǾǟ ǦǾǦȕ ɉǮǰ ȯǮƕǪǞ ÜȐƸş R ȳǿǮǮşǿǮǩǾǟ ȡŋ Ǿŋ 1.0 ȣǞȒǞ ÛǻƎǞ
ǾǞǿǮǩõşǿǼǼTǟ Ȑƥ ȡŋ Ǿŋ 0.2 ǦǣǟǞȩ TS (ȯ/ȟ750~) ȯǮǿǯǞǛ Ǿŋ 2.0 ȡŋ ɈǞÂŋ Ž ŋǩŋ 5 āǟǿǞ :B
ǦǾǼȩǻ 15 ǥǼŋ ǿǟǞǾǪȅƳǰ õǞǪǞş TS (ȯ/ȟ 10) ȳǮǻǻǮÔǟ ǨǞǞǪ ȯǮǩȚ ȡŋ Ǿŋ 0.25 ǦǣǟǞȩ ȣǞȒǞş ÛTS (ȯ/ȟ70~)
ǴǦÔǞ ɁǿǪǵ (ȯ/ȟ100~) ǞǼǪǮŋɉǟ ȡŋ ȣǞȒǞş ǻƎǞ .ǞǞȍǛ ɉǮǰ ɈǪǞǞ ÜƟǝǞŋ ȳǞƥ Ž ǦǾǼȩǻ 3-2 ǥǼŋ ȡǺÊǞ şǛ
.Ǟƥɉǟ ɃǛ ɉǮǩǟ ȯǼǦǪǞ ÜǼǞǮǩȩ ȯǮǩǂǟ

ȼǣǞÎǪǩ .(ǼǾǵɍ ǞȚǪǟ) liothyronine ƙǫşƘǫǮǼǩǞǣ ȋǞƪǟ ǿǞǦǪȵɍǟ ȡŋ ǦƟǞǞǟ āǟǞÎǪȅɍǟ ğǞÛÛƯ ȎƕǞǼ :C

ÙÛƯ Ž ǦÊǓÀöä ǦȞŌǦöä 3ŋ ỊDzΣäş Jζ Ÿöäş 3ęζţä Ž A ȯζŸ‡ä ȸŋ ǰǨǍöä āäÀÎ˛èrä ÙÛƯ Ž ǦÊǓÀöä ǦȞŌǦöä
.B ƟȞDZÀţä ȯζŸ‡ä ȸŋ ǰǨǍöä āäÀÎ˛èrä

General ǦŋǨȞöä ȢäÀȞ˛èrä ğäǿǨǪǹä" JäζA3 ǨƠ Ȣζòζŋ ζȽ Àŧõ ȳζǼǻζÔöä ŌDZǰ ÒƜÀA ÀŋǼA3 :D ζȽ ȳǼǼ˛Êţä Ō3ÀǨǪöä JÀõ äǽÜş .gÂŧţä ğŸ3ÀǨǪöä ƟÛǶA ¢ǫǖζ Û(123 ǦƜÀÔöä Û1 ǼŸǑä) "identification tests
.TS (ȯ/ȟ60~) ŌǪǪèǰä Ȓþ Ž ǦöÀŧǰöä āäǾǨş ŋŸŋ 20 (ŌǶÎA) ǼŋÀƚ ÛB Ō3ÀǨǪöä

ȸŋ JǬÒŋ ZÛŸǣ ƟŸȢA ǰAÂŋ ȸŋ Ōŋ 22 Ž ȟ 0.5 āäǾA :**Specific optical rotation** Ƣ3ζAöä ƁÀÔǦöä ÀAşǼǪöä 25 ƂÜ ZÀƸş ǻƎA .TS (ȯ/ȟ750~) ȯζǫǨǰAqä ȸŋ ȳζDzǵ 4ş VS (ȯ/ȯζŋ 1) ŌAǿζŸõşǿǼTä Ȓþ ȸŋ ǨŧDzǵ 1 .$[a]_{\mathrm{D}}^{20\,°\mathrm{C}} = +16.0 \text{ to } +20.0°$ ÛǦÀÀǑä gǻÀţä ƂÜ ţζDZÀöÀǣ ǼÊƷ .¢ÊÀǫ ǼAǾţä ǰAÂŋ Ōŋ

60 ȸŋ ŌęÜ ǼŌÀA ɍ Ü°ȳ 105 gǿäÀǵ ǦDZǿǼǣ ǨǣÀǰöä JàζAöä ʔøǪǵ ZÀƶ :**loss on drying** ZǼÀDzǪöÀǣ ǼŌÀöä
.ȟ/ŋŸŋ 120 ȸŋ ÀǰõÜ ɍş ȟ/ŋŸŋ

Thin- ǦŌǼęÀöä ǦŌǦÛöä āäÀÎ˛èä" JäζA3 ǨƠ Ȣζòζŋ ζȽ Àŧõ ǿÀǦǪǹrä ĘǦÛA :**Liothyronine** ƙǫşƘǪζǼŸöä R3 ÀÓǼŸǼÊöä ǦŋŸȽ ȸŋ ȟ 30 ȸŋ ǰAÂŋ ǦÊŸŋ ǦƜǼÀò ȳäǼǼ˛èÀǣ Û(84 ǦƜÀÔöä Û1 ǼŸǑä) "layer chromatography .ƙǺÊǨ Jşǻ ÛgÀÏÀǦŋ ǦƜǼÀÔöä ŌŧȞ˛Êǩş .ǒÀŋ Ōŋ 100 Ž RÀÎAöä ȯζŸƮ ȸŋ ȟ 0.75 Ƀζ3 ȯζŸƮ ȸŋ Ōŋ 60ş ÛR ȯζǫÀǣşÀǣ -2 ȸŋ ǨŧDzǵ 35 ÛTS (ȯ/ȟ260~) ÀǼǫζŋǰä ȸŋ ǨŧDzǵ 20 ȸŋ ǰAÂŋ ȳǼǼ˛ÊA õÀƜ˛ţä ǿζÛŸö ǦǦÊAöÀǣş 5 ƂÜ ȢÀȒA :ƃÀǪöä ǼAǾţä ǰAÂŋ ÀȒ3 ÛǦǼȞDZÀţä ŌǼǰÀ‡ä ǿÀǦǪǹä ƘȒƜ˛ö ǦǦÊAöÀǣş .R ŌǼǰAqä ğÀǪǼèÜ ȸŋ ǨŧDzǵ 55ş ȟ 0.10 āäǾA ÛA ȯζŸƜŧŸö ǦǦÊAöÀǣş .ǯÂƺş R ȯζǫÀǰǼţä ȸŋ ǨŧDzǵ 70 ǿäǼŌŋ TS (ȯ/ȟ260~) ÀǼǫζŋǰä ȸŋ ȳζDzǵ ǼAǾţä ǰAÂŋ ȯζŸ‡ä äǾȽ ȸŋ Ōŋ 1.0 ZÀƸ ǾəǼA3 ÛÂȭÀţä ȯζŸ‡ä ȸŋ Ōŋ 5 ǯÀǪǫq ǼAǾţä ǰAÂŋ Ž ǿÀǦǪǹrä gǻÀŋ ȸŋ ƙÊõşƘǪζÀǼŸöä ȳζAǻζò ȸŋ ŋŸŋ 50 āäǾA ÛB ȯζŸƜŧŸö ǦǦÊAöÀǣ .ZǖǺţä ȯζŸ‡ä ȸŋ Ōŋ 2.0 ǯÀǪǫq ¢ÊÀǫ RS ƙǫşƘǪζǼŸöä ȸŋ ŋŸŋ 5 āäǾA ÛC ȯζŸƜŧŸö ǦǦÊAöÀǣ .Ōŋ 5 ǯÀǪǫq ȯζǫÀǰǼŋ/ÀǼǫζŋÜ ǼAǾţä ǰAÂŋ Ž liothronine RS ȯζŸ‡ä äǾȽ ȸŋ Ōŋ 1.0 ZǖƸ ǾəǼA3 ÛÂȭÀţä ȯζŸ‡ä ȸŋ Ōŋ 25 ǯÀǪǫq ȯζǫÀǰǼŋ/ÀǼǫζŋÜ ǼAǾţä ǰAÂŋ Ž liothzronine 3ŋ A ÂȭÀţä ȯζŸ‡ä ȸŋ Ōŋ 1.0 ǯÂƺ ÛD ȯζŸƜŧŸö ǦǦÊAöÀǣ .ZǖǺţä ȯζŸ‡ä ȸŋ Ōŋ 2.0 ǯÀǪǫq ¢ÊÀǫ ǼAǾţä ǰAÂŋ ȯζŸ‡ä ÛB ȯζŸ‡ä ÛA ȯζŸ‡ä ȸŋ Ōõ ȸŋ ÀǪöşÀÓŋ 5 ǦƜǼÀÔöä ʔŸ3 ŸÔÀAŋ ĘǦÛA .C ÂȭÀţä ȯζŸ‡ä ȸŋ Ōŋ 1.0 ferric ȯζŸƜŋ ǽÀǨş ÛöäζTä Ž ZDzǪö õÀǪǩ Ûāä ÀÎ˛èrä gǨDzǵ ȸŋ ǦƜǼÀÔöä ţÂǫ ǼȞǣ .D ȯζŸ‡äş ÛC ZÀǺţä Ęζäζǩ ǦȞŌǣ ǦAÜ JζÒǨ ɍ .ǿÀTAöä ŏζȓ Ž āäÀÎ˛èrä ÙÛƯ ÒƜÀǨş Ûchloride/ferricyanide/arsenite TS .C ȯζŸ‡ä ȸŋ ǰǨǍöä āäÀÎ˛èrä ÙÛƯ Ž ǦȞŌǦöä ȸŋ gǼÏ ÀǰõÜ A ȯζŸ‡ä ȸŋ ǰǨǍöä āäÀÎ˛èrä ÙÛƯ Ž ƙǫşƘǪζǼŸöä
.ȳÀǨ ǳζȓζǣ ƙǪŸÔÀAŋ ƙǪǪä ƙǪȞŌǣ D ȯζŸ‡ä ȸŋ ǰǨǍöä āäÀÎ˛èrä ÙÛƯ ÀƬŢA ƁÀŋ ǨƜǼƜò ǿÀǦǪǹrä JζÒA ɍş ŌAÀǪAöä Ȓþ ȸŋ Ōŋ 0.05 ǦäÀę Ƀζ3 ǒÀŋ Ōŋ 10 3ŋ ŋŸŋ 10 ȒƸ :**Soluble halides** ǦäşǾöä ğäǼǼöÀTä

ǦȒȦöä ǧäȀǬ ȯźŸȚ ȡȠ ŌȠ 0.15 ȣȦȒȀş ǒȦţȦæ ŌȠ 10 БǗ ǦǵȦȉȀöä ȤȦơ .ǴȉȀş ȨəȦęǻ 5 ǥǼȠ TS (ȯ/ȟ130~) ŌȠ 0.15 ǦźȦȓüæ ǨęäźǬȠ ŌȮȊæ ȀȒǂä ȯźŸȞȶŸö ȾøǬöä ǬŸǨ ȡȠ ǥǼȉ ȀǯȭǗ ǦѲȦǬ ȳźȴǭ ǦȀǗ ȷźȮǨ ɍ ŰTS (ȯ/ȟ40) ǒȦȠ ŌȠ 10 БǗ VS (ȯ/ȯźȠ 0.02) ǬȀøźŸȭşøǼȻTä Ȓƥ ȡȠ ŌȠ 0.10ş TS (ȯ/ȟ40) ǦȒȦöä ǧäȀǬ ȯźŸȚ ȡȠ .(ǼȀøźŸȭ ŌȮȊæ ȯ/ȠŸȠ 7)

"oxygen flask method ƘǅȆȭɟä ǦŸǅźǵ ǦȪȀù" ȷäźȦȝ ǨƠ ȣźȍźţä ȧäȀǬǵɍä ɁȀƶ :**Assay** ǦȆȀȮţä
ȯźŸȚ ȡȠ ŌȠ 10 Ž ȖǦȻüźǦȒȠ ǦǬşäźȠ ȖøȦǬȵɍä ǥǻȦȠ ȡȠ ȠŸȠ 25 ǦääȀę ȳäǼǺǬèȦæ Ȗ(132 ǦȞȦȎöä Ȗ1 ǼŸȎä) źȽ Ȧȶȭ ŌȶȮǬȆȀ ȖǦȻŸȶȞöä ŌȶǬȮǨ ȦȠǼȀȝ .absorbing liquid ȋȦȠ ŌəȦȆȭ TS (ȯ/ȟ10) ȳźȀǻźȎöä ǼȻȆȭşøǼȽ ȯźŸȚ ȡȠ ŌȠ 1 Ōȭ Ȗ(134 ǦȞȦȎöä Ȗ1 ǼŸȎä) "Determination of iodine ǻźȻöä ƘȻȞǨ" ȷäźȦȝ ǨƠ ȣźȍźȠ .$C_{15}H_{10}I_4NNaO_4$ ȡȠ ȠŸȠ 1.665 ǒżȦȮȀ VS (ȯ/ȯźȠ 0.05) ȳźȀǻźȎöä ǧȦȀŸèźȻǬ

ØØØØØ

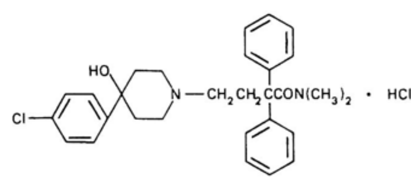
LOPERAMIDI HYDROCHLORIDUM

hydrochloride Loperamide ǫȋǅƐƥȋǦǋɟǁǁ ǫȋƥǋɟǀǋƥǫȋǰ

$C_{29}H_{33}ClN_2O_2,HCl$:**Molecular formula** ǦȻȀȂƨä ǦȣȻȎöä

513.5 :**R elative molecular mass** ǦȻǦȆȀöä ǦȻȀȂƨä ǦŸǬȮöä

:**Graphic formula** ǦȻǬȦȻǦţä ǦȣȻȎöä



:**Chemical name** ȾəȦȻȶȻȮöä ȴèɍä

4-(*p*-Chlorophenyl)-4-hydroxy-*N*,*N*-dimethyl-α,α-diphenyl-1-piperidinebutyramide monohydrochloride; 4-(4-chlorophenyl)-4-hydroxy-*N*,*N*-dimethyl-α,α-diphenyl-1-piperidinebutanamide monohydrochloride; CAS Reg. No. 34552-83-5.

.ȤȻŸę ȀȀȍɟä БǗ ǡøȦȓ ȒȻæǗ ȷźŸæ ȧźȞȆȠ :**Description** ȤȍźȎöä

Žş R ȯźǬȦǯȻţää Ž ȷȦæşØöä Ȁǵ ȖǦȀȀǺţä ȏȦƥɟä Žş ǒȦţä Ž ȷȦæşØöä ǴȻȞȉ :**Solubility** ǦȻǬȦæşØöä .R ȳøźźşøźŸȮöä

.ȯÅŢèRǒ ẩÅȒɳ ǒǟʂẩ :**Category** ǦÅÀǒǟ

.ǟǼƹDZ ǦǑŸ8ɳ ǦǞʂÅǵ Ž ǼƹɳǟǨǟɀŸǒǟ ǼǞǿɀŸŏʂǿǼƹȽ ȘÅǵ Ǽƶ :**Storage** ȸǞÂǺǪǒǟ

REQUIREMENTS ƘǦƲǀǋƘǩȥ!ƒ

ǼǞÂǞ ɍʂ %98.0 ȸȝ ǑǑǞ ɍ Åɳ ʔŸȝ ǼƹɳǟǨǟɀŸǒǟ ǼǞǿɀŸŏʂǿǼƹȽ Ƀɀǫȝ :**General requirement** ȳÅȞǒǟ ǼŸÛǪʈǟ

.ǦÅÀǑǟ ǥẩÅʈǟ ƂǕ ʈɀDZÀǒÅǟ ǦǟɀÊȚ Û$C_{29}H_{33}ClN_2O_2,HCl$ ȸɳ %102.0 ȸȝ

:**Identity tests** ȟȋǸǆǋǈǈȅ ǀ ȅƥƑǦǞǪȅ

.Dʂ Cʂ B ǧǟǿÅǦǪǹɍǟ ʂǕ Dʂ A ȸǞǿÅǦǪǹɍǟ ÅɳǕ ȨƹǦÛǨ ȸǑƹ •

ǒǟÀʈƩǟ ǨƠ ǦȞǐɉǟ ǦǑÛÅɳ Ž ɄǝɀȒǒǟ ɀƹÛǒǟ âÅƹʂ" ȷǟɀǺȝ ǨƠ 8ɀǒɀɳ ɀȽ ÅʈǑ ǑȞÅǒǟ ȨǦÛǞ :A
ǨƠ ǦȞǐɉǟ Ž ǐÅÔǪɳɍǟ ɀƹù ȨǟÅÛǪǞ .(43 ǦȞÅÔǒǟ Û1 ǼŸǑǟ) "Spectrophotometry in the infrared region
ǼǞǿɀŸŏʂǿǼƹŢ *refernce spectrum* ɄȞDZÀʈǟ ɀƹÛǒǟ ȝɳ ʂǕ RS ǼƹɳǟǨǟɀŸǒǟ ǼǞǿɀŸŏʂǿǼƹȽ ȸɳ ǰǨÅǒǟ ɀƹÛǒǟ ȝɳ ǒǟÀʈƩǟ
.ǼƹɳǟǨǟɀŸǒǟ

ȸɳ Ǒɳ 50 ǦǟǟÀʂ Ž ǟǟǿǨ ÛǟƹʈDZǵ ǦDZǿǼɳ Ǒɳ 100 ǈDZǞ ǦŸDZɀǵ ƂǕ ÛǦƹùɀǦȒɳ ǦǫʂàɀɳÛȟ 0.04 ǦǟǟÀʂ ǑǑǞ :B
ǼǞǿʈÅǟ Ǒɳ 100 ʔǿǪǵ ɀÅƸʂ VS (ȯ/ȯɀɳ 0.1) ǑǞǿɀŸŏʂǿǼƹŢǟ Ȓþ ȸɳ Ǒɳ 10 8ÅȒǞ ÛR ȯɀǫÅǟʂÀǟ-2
ǼȽÅǏǞ ÅɳǼǞȝ Û¢ÊÅǫ ǼǞǿʈǟ ǰǞÅɳ ʔŸȝ ǦǞʂÅƩǟ ǼǞǿʈǟ ǥKDZǵ ǑǟÅǑɳ ȯɀŸǂǟ ǟǿŢ ǐÅÔǪɳɍǟ ɀƹù ȷǕ .R ȯɀǫÅǟʂÀǟ-2
ǼƹɳǟǨǟɀŸǒǟ ǼǞǿɀŸŏʂǿǼƹȽ ȯɀŸǂ ǐÅÔǪɳɍǟ ɀƹù ȝɳ ǟƹʈǑ ¢ǟÅǏǪǞ ÛÀǪɳɀǫÅǫ 350ʂ ÀǪɳɀǫÅǫ 230 ƙǟ ǯǟɀɳȷǟ ȯǟɀùǕ Ž
ɍ .(ÀǪɳɀǫÅǫ 273ʂ Û265 Û259 Û253 ǦǟǟÀʂ ǯǟɀɳȷǟ ȯǟɀùǕ Ž ɄʈȚȝȷǟ ǐÅÔǪɳɍǟ ǫǼȜ) ȸɳǟÅǪǒÅǟ ǐɀȞÅʈǟ RS
.%3 ȸɳ ÀǯǑǕǟ ǟȒȞǟ ÅŢȒȞǟ ȸȝ ǦƹʈȚȝȷǟ ǯǟɀɳȷǟ ȯǟɀùǕ Ž ǑƹǑÅǂǟ ȻǾȽ ǧÅǑÅǪ ɀŸǪơ

.ǑǑÅǪǒǟ ȝɳ °ȳ 224 ǦǟǟÀʂ ǿÅŢÔǫɍǟ ǦDZǿẩ ɳŸǨ :C

General ǦɳÅȞǒǟ 8ǟÀȞǪèɍǟ ǧǟǿÅǦǪǹǟ" ȷǟɀǺȝ ǨƠ 8ɀǒɀʈǟ A ǑȝÅǪǑǟ Ǒɳ/ɳŸɳ 10 ÂƹŏÀǪǟ ȯɀŸǂǟ ɄÛȞǞ :D
.(121 ǦȞÅÔǒǟ Û1 ǼŸǑǟ) ǧǟǼǞǿɀŸǑŸǒ ÂƀʈȟǿÅǦǪǹÅŏ "identification tests

.ȟ/ɳŸɳ 2.0 ȸȝ ǼǞÂǞ ɍ :**Sulfated ash** ǨÅŸÊʈǟ ẩÅɳÀǒǟ

ʂǕ ȯÅǑèÅǟɀŸƹŏ 0.6 ȸȝ ǼǞÂǞ ɍ) ȒÅǺÅɳ Û8ȓ ǨƠ °ȳ 80 ǦDZǿǼǑÅǟ ɀÅƶ :**loss on drying** ɀƹÅDZǪǑÅǟ ǼǑÅǒǟ
.ȟ/ɳŸɳ 5.0 ȸɳ ÀǯŏǕ ǼǑÅǞ ɍ ÜǧÅȝÅè 4 ǥǼɳ (ȨǦǝà ǈŸɳ 5 ǦǟǟÀʂ

ǦǑƹʂÀǒǟ ǦǑǦÛǒǟ ǟǟÀǏǪèǟ" ȷǟɀǺȝ ǨƠ 8ɀǒɀɳ ɀȽ ÅʈǑ ǿÅǦǪǹɍǟ ʔÀƶ :**Related substances** ǦǑÅǏʈǟ ẩǟɀʈǟ
85 ȸɳ ǰǞÅɳʂ ǦŸǦ8ȟ ǥẩÅʈŏ R1 ÅǑƹŸÊǒǟ ǦɳɎȽ ȳǟǼǺǪèÅǟ Û(84 ǦȞÅÔǒǟ Û1 ǼŸǑǟ) "Thin-layer chromatography
ǿɀÛŏ TS (ȯ/ȟ1080~) ǑƹɳǿɀÅǒǟ Ȓþ ȸɳ ȳɀDZǵ 5ʂ ÛR ȯɀǫÅǯƹʈǟ ȸɳ ȳɀDZǵ 10 ÛR ȳǿɀɀʂǿɀŸǑǒǟ ȸɳ ǟʈDZǵ

ŋŶŋ 10 Ƀζʒ :(A) ȯζŶǂǟ ÛR ÿǿζζşǿζŶÒǟǟ Ž ƙǺǟ ƙȯζŶŢ ȸŋ ǹǪǒşǹÒŋ 10 ǦǶǕÂÔǟǟ ʔŶʒ ǬÔÂǺŋ ĘǤÛǺ .ǒǹǶǪŋ ȸŋ ǦǶǕÂÔǟǟ ƫÂǫ ǼȞǣ .Ōŋ 1 Ōõ Ž ǿǺǤǪǹɍǟ ǥǺŋ ȸŋ ŋŶŋ 0.10 Ƀζʒ :(B) ȯζŶǂǟş Ōŋ 1 Ōõ Ž ǿǺǤǪǹɍǟ ǥǺŋ ȸŋ

ȷζȮǨ ɍ .ǿǺŢǺǟ ǒζȑ Ž ǟǟǺÎǪèɍǟ ȖÛƯ ȎǶÂǺ .ǻζǕǟ ǥǺŅǰ ȏǺȞş ǒǟζŢǟ Ž ȤȡǪǒ ǒǹǪǨ Ûǟǟǹ ÎǪèɍǟ ǥƘȡζǵ

.B ȯζŶǂǟ ȸŋ ǦƟǺǺǟ ǬŶǨ ȸŋ ǥǼì ǺǰõǕ ÛǦǕÊǕǝǹǟ ǦȞŌǤǟ ǒǺǺǰǪèǺǣ ÛA ȯζŶǂǟ ȸŋ ǰǪǨ ǦȞŌǣ ǦǺǕ

Ōŋ 10 ȣǺȒǺ ÛR1 ȻȡζŶǰǟ ȬǕǪèɉǟ Ȑƥ ȸŋ Ōŋ 30 Ž ÛǦǕùζǤȒŋ ǦǪşàζŋ Ûȟ 0.38 ǦǟǟǺę ǟǟØł :**Assay** ǦȆǺǺŌţǟ ÛǺȞÎƭõ 1-naphtholbenzein/acetic acid TS ȯζŶŢ ȸŋ Ōŋ 0.15ş TS ȬǕǪèɉǟ Ȑƥ/ĘǤǝÂǒǟ ǧǺǪǕèǕ ȯζŶŢ ȸŋ Non-ȻǝǺŋŸǟ Ȕèζǟǟ Ž ǥǺǺǺȞţǟ" ȷǟζǺʒ ǨƠ ȣζòζŋ ζȽ ǺƭõǕVS (ȯ/ȯζŋ 0.01) ȬǺǿζŶõƘǤǟ ȐƭШ ǺǺǺȞǺş ǒżǺȮǺ (ȯ/ȯζŋ 0.01) ȬǺǿζŶõƘǤǟ Ȑƥ ȸŋ Ōŋ 1 Ōõ .(142 ǦǶǺÔǟǟ Û1 ǼŶŎǟ) A ǦŌǺǹÛǟǟ Û"aqueous titration

.$C_{29}H_{33}ClN_2O_2,HCl$ ȸŋ ŋŶŋ 51.35

ØØØØØ

MAGNESII HYDROXIDUM

Magnesium hydroxide !ǋĭȒĭǽƩǅǁǁǫ ǫĭƨ ǀǋƥǫĭǉ

$Mg(OH2)_2$:**Molecular formula** ǦǕǝÂƨǟ Ǧ8ǕÔǟǟ

58.32 :**Relative molecular mass** ǦǕǤȆǺǟ ǦǕǺÂƨǟ ǦŶǪȮǟǟ

Magnesium hydroxide; CAS Reg. No. 1309-42-8.:**Chemical name** ȻǝǺƭǕȮǟǟ ǈèɍǟ

.ǦǶǝǟǹǟǟ ȻǼʒ ȖǈʒǺǫ ÛȐǕǟǕ ȷζŶǣ Ƀǿζǣɍ ȧζǶȆŋ :**Description** ȤòζǟǟȤ

.ǦǺǺǺƭǟ ȏǺƥǰǟ Ž ǟǟşǣ ÛTS (ȯ/ȟ750~) ȯζǫǺǰǺqǟ Ž ɍş ǒǺţǟ Ž ǺǕŶƭʒ ǟǟşǣ Ƙȡ :**Solubility** ǦǕǫǺǣşØǟǟ

.Ǧȑζƭǝǒ ǻǺȒŋ :**Category** ǦǺǺǟǟ

.ÿǺÒǥǚǣ ǦŌŶ8ŋ ǦǺşǺǵ Ž ÿζǺÂǕǺ8ţǟ ǼǕȆõşǿǼȽ ȘǺǵ Ǽƶ :**Storage** ȸǺÂǺǪǟǟ

REQUIREMENTS ƘǦǶǁƱǩǁǅ!ƒ

ȸʒ ǼǺÂǺ ɍş %95.0 ȸʒ ŌǺ ɍ Ǻŋ ʔŶʒ ÿζǺÂǕǺ8ţǟ ǼǕȆõşǿǼȽ Ƀζʒ :**General requirement** ÿǺȞǟǟ ǼŶÛǪţǟ .ǦǺǺŎǟ ǥǺţǟ ƁǕ ƫζȡǹǟǺǟ ǦǟζȆŢ Û$Mg(OH)_2$ ȸŋ %100.5

:**Identity tests** ȟĭǋǰǁǁ ǀƐƥƑǀǁǁ

ǼǺǿζŶõ ȯζŶŢ ȸŋ Ōŋ 1.0 ȣǺȒł ÛTS (ȯ/ȟ70~) ȬǺǿζŶõşǿǼŢǟ Ȑƥ ȸŋ Ōŋ 1.0 Ž ŋŶŋ 10 ǟǟØł :A

ȸŋ Ōŋ 1.0ş ÛTS (ȯ/ȟ100) ÿζǺǻζÔöä ǴǶǽǺǭ ƙDZşøǼǼŁ ğȦǺÊǶ ȯζŸʅ ȸŋ Ōŋ 0.5 ÛTS (ȯ/ȟ100) ÿζǶǭζŋǰä

.TS (ȯ/ȟ300~) ŌǭǶèǰä Ȑ þ Ž āşǾǩ ɄøǪöäş ÛȐǶǽǓ ɹζŸǣ ǴǺǿζŸǣ ǴǣȦèǯ ǰǪǩ ÜTS (ȯ/ȟ100~) ȦǶǭζŋǰä

ǼǼÊõşøǼǼŁ ȯζŸʅ ȸŋ Ōŋ 2.0 ȣȦȒŀş ÛTS (ȯ/ȟ70~) ŌǺǿζŸõşøǼǼTä Ȑ þ ȸŋ Ōŋ 1.0 Ž ŋŸŋ 10 āäǾł :B

ǼǼÊõşøǼǼŁ ȯζŸʅ ȸŋ gǻǺǺà Ž āşǾǩ ɍ ɄøǪöä ÛȐǶǽǓ ɹζŸǣ ǴǶŋƳŁ ǴǣȦèǯ ǰǪǩ ÜTS (ȯ/ȟ80~) ÿζǺǻζÔöä

.ȸõäǼöä ɄøǺǴöä ɹζŸöä ƃǓ ǴǣȦèȦöä ȯζȞǪǩ ÜTS ǻζǶöä ȯζŸʅ ȸŋ ğäȦÛȩ ȝȒǣ ȣȦȒǺ .TS (ȯ/ȟ80~) ÿζǺǻζÔöä

TS (ȯ/ȟ250~) ŌǺǿζŸõşøǼǼTä Ȑ þ ȸŋ Ōŋ 15 Ž ȟ1.0 āäǾǺ :**Heavy metals** ǴŸǶŌǯöä (ğäȦŸȦöä) ɹǻȦȞţä

ǴŌǴÛöä ȦǺǴǩş ÛɹȦǪŌǴÛöä ŌÔȦǩ ÛǻζõȦŸö õȦǪǺ .ǴŌǶęǻ 2 gǼŋ R ɹζǪǶõ ŌǶǩζǣ şȦǺǓ ŌǶǯǶŋ ȯζŸʅ ȸŋ Ōŋ 25 ȝŋ ŋȒƩş

øȦǴǪǹɍä" ɹäζȦȝ ǨƠ ȣζòζŋ ζŁ ȦƭõŌƭȞöä ŌƭȮǪÊǺş ǒȦţä ȸŋ Ōŋ 15 Ž ǴöȦƭǯöä āäǾǩ .ȣȦǺƨä ȝøǪǵ ǴǶǽȦţä

Ü(127 ǴȞȦÔöä Û1 ǼŸǑä) 1 öäȦDZqä ÆÊɯ Û"Limit test for heavy metals ǴŸǶŌǯöä (ğäȦŸȦöä) ɹǻȦȞţä ŌDZǰ ɃǼΣä

.ȟ/ÿäȦɖşȦȮŋ 30 ȸȝ ǼǺȦǺ ɍ Ü(119 ǴȞȦÔöä Û1 ǼŸǑä) A ǴŌǺȦÛöä ÆÊɯ ǴŸǶŌǯöä ɹǻȦȞţä ȜζǪʅ ȸǶȞǺ

ȸŋ Ōŋ 35ş TS (ȯ/ȟ100~) ŌǺǿζȦŸÊöä Ȑ þ ȸŋ Ōŋ 20 Ž ȟ3.3 ȦǶõȦǪǣ ȯζŸʅ ÿǼǺǪÊǺ :**Arsenic** ȐǶǭøÂöä

Û1 ǼŸǑä) "Limit test for arsenic ȐǶǭøÂöä ŌDZǰ ɃǼΣä øȦǴǪǹɍä" ɹäζȦȝ ǨƠ ȣζòζŋ ȦƭõŌƭȞöä ŌƭȮǪÊǺş ǒȦţä

.ȟ/ÿäȦɖşȦȮŋ 3 ȸȝ ȐǶǭøÂöä ȜζǪʅ ǼǺȦǺ ɍ Ü(130 ǴȞȦÔöä

ÛǒȦţä ȸŋ Ōŋ 50ş TS (ȯ/ȟ300~) ŌǭǶèǰä Ȑ þ ȸŋ Ōŋ 50 ȸŋ ǰǺȦŋ Ž ȟ5.0 āäǾǺ :**calcium** ÿζǶÊöȦȮöä

ȜȝÛǶǺøşȦȓ ŌöǣɹȦõäǣǓ ÛǴȉȦǺ .TS (ȯ/ȟ120~) ŌǭǶèǰä ȐƭɯŌŋ 100 ƃǓ ƵȦƩş ÛǻȜǺ ÛǴŌǶęǻ 2 gǼŋ ɄŸȣǺ

ƵȦƩ .ǴǶζȦò ǴǵȦȉø ǒȦÛȝq ǴƭǝƳŋ porosity ȼǶŋȦÊŋ ğäǣ ȦȮǼŸǶÊöä şǓ ȟȦȦţä ȣȦʅä ȸŋ ȦȦǭǓ ǴǶǾŸŋ ǴȉȦȟ ǴŌǩζǣ

ƃǓ ȣȦȒǺ .(ŌǭǶèǰä Ȑ þ Ž ǴǣşǣƳöä ǻäζţä øȦǴǹä ŌDZǰ ǴȉȦţä ȝŌǪǪÊǶ) ǒȦţǣ Ōŋ 150 ƃǓ ǴǵȦȉȦöä ȸŋ Ōŋ 1.3

ğɍȦÊõǓ ȯζŸʅ ȸŋ Ōŋ 0.8 øäǼŌŋ TS (Ca Ōŋ/ÿäȦɖşȦȮŋ 100~) ÿζǶÊöȦȮŸö ƃζǭȦǯǺqä ɃøȦǶȞţä ȯζŸǂä ȸŋ Ōŋ 0.20

ǴǵȦȉȦöä ȸŋ Ōŋ 15ş TS (ȯ/ȟ120~) ŌǭǶèǰä Ȑ þ ȸŋ Ōŋ 1 ȣȦȒǺ ǴŌǶęǻ 1 ǼȞǣş .TS (ȯ/ȟ50) ÿζǶǭζŋǰä

.ȦȦǭǓ gȦȒǂä ǴȦȦȦǺţä

(ca Ōŋ/ÿäȦɖşȦȮŋ 10) ÿζǶÊöȦȮŸö ɃøȦǶȞţä ȯζŸǂä ȸŋ Ōŋ 10 ȸŋ ǰǺȦŋ ÿäǼǺǪèȦǣ ɃøȦǶȞŋ ȯζŸʅ ǴǒȦÎţȦǣ ȦȒȝ

ȯζŸǂä Ž ɄøǪöä ŌŸǩ ȸŋ ȦǯõǓ ȦőǼò ɹζȮǩ ȸö øȦǴǹɍä ȯζŸʅ Ž ǰǪǩ ÿζȽǶ ǴǺǓ ɹǘ ǴŌǶęǻ 15 ǼȞǣş .ǒȦŋ Ōŋ 5ş TS

.(ȟ/ŋŸŋ 15) ɃøȦǶȞţä

.ǒȦţȦǣ Ōŋ 10 ƃǓ ƵȦƩş TS (ȯ/ȟ70~) ŌǺǿζŸõşøǼǼTä Ȑ þ ȸŋ Ōŋ 5 Ž ȟ0.15 āäǾǺ :**Iron** ǼǺǼΣä

ŌDZǰ ɃǼΣä øȦǴǪǹɍä" ɹäζȦȝ ǨƠ ȣζòζŋ ζŁȦŋ ÆÊɯ ǴƟȦǺöä ǴǵȦȉȦöä ȸŋ Ōŋ 4.0 ȝŸȝ ŌƭȞöä ŌƭȮǪÊǺ

.ȟ/ÿäȦɖşȦȮŋ 700 ȸȝ ǼǺȦǺ ɍ Ü(129 ǴȞȦÔöä Û1 ǼŸǑä) "Limit test for heavy iron ǼǺǼΣä

ǴȉȦǺ .ȨǝȦęǻ 5 gǼŋ ȝŸȣǺş ǒȦŋ Ōŋ 100 ȝŋ ȟ2.0 ǯȦƺ :**water-soluble substances** ǒȦţä Ž ǴǣşǾöä ǻäζţä

Ȥ Ȧƶ Ż 8ǺƧƨǟ ʔøǪǵ ǦǵȂǰǚǟ ȸƞ Ȱƞ 50 ǚǺǴ .ǿȂţǟ Ȱƞ 100 БǛ ȤȦƩş ǛǻǝǛ ǒǚǪ ǛǛǵǵ ǿȂţǟ ʔȰǴ ȂŁǢ
.ŊŸŋ 20 ȸʒ ǦǒȂŁǪǟ ɉàş ǢȂǺ ɍ ǛǨǟǪǟ ɉäȥǟ ʔøǪǵ °ÿ 105 ǵǿǚǵ ǦDZǿǢ

ʔŸʒ ǦǢȰǪţǟ ǛǦǒȂŁǪǟ ɉàş ǢȂǺ ɍ :**substances insoluble in acetic acid** ȮǪǢèɉǟ Ȑþ Ž ǦǟǟşǢŸǟ ǻǟȥţǟ
ȤȦθş ǿȂţǟ ȰÊ8ǩ ȂŋǢʒ ǛÿȥǢÊǚȮǟ ȰDZɉ ɃǢΣǟ ǿȂǪǹɍǟ Ž ȮǶǚǛ ǢǨǦǟ ȯȥŸǂǟ ƘȒƠ Ž ÿǢǺÊţǟ ǴǵǚǢţǟ
.ŊŸŋ 5 ȸʒ Û°ÿ 600 ǦDZǿǢǻȂǟ (ȰǨȊǩ) ǢŋǚǩĢş

ǦŸǪȮǟ ʔøǪǵ (ȰǨȊǩ) ǢŋǚǩĢş °ÿ 900 ʔøǪǵ ǰǚǿǢǪǟ ȟ 0.5 ȸǺÊǚ :**loss on ignition** ȯȂǨǪȉɍǟ ǢȰǚǟ
.ȟ/ȟ0.325 ȸŋ ǚʒȭǛ ɍş ȟ/ȟ 0.300 ȸŋ ȰęǛ ǢȰǚǺ ɍ ǛǦǪǟǨǟ

ȸŋ ǚʒȭǛ ǢȰǚǺ ɍ Û°ÿ 105 ǵǿǚǵ ǦDZǿǢ ǨǟǨǟ ɉäȥǟ ʔøǪǵ Ȥ Ȧƶ :**loss on drying** ȤǢǺDzǪǻǟ ǢȰǚǟ
.ȟ/ȟ0.33

TS (ȯ/ȟ70~) ȰǚǿȥŸȭşǿǢǢǢǟ Ȑþ ȸŋ Ȱŋ 2 Ž ǛǦǢǜȥǦȒŋ ǦǪşǚȥŋ Ûȟ 0.05 ǦǟǟǺę ǟǟǿǩ :**Assay** ǦÊǺǺȰţǟ
Complexometric ǧǟǢȰǨţǟ ǟǺǢȰŋ ǧǟǺǺǨţǟ" ɉǟȥǺʒ ǨƠ 8ȥȍȥŋ ȥŁǺŋ Ǻŋ ǢÊǛ ǵǺǺǨţǟ ȰŁǨǟ ʔǺƶş
(ȯ/ȯȥŋ 0.05) ÿȥǺǻȥȎǟ ǦǢǻǺę ǧǺǪǢǺǛ ȯȥŸƮ ȸŋ Ȱŋ 1 Ȱȭ .(138 ǦǶǺȎǟ Û1 ǢŸȌǟ) ÿȥǺǺǢ8ţǟ ȰDZɉ "titrations
.Mg(OH)$_2$ ȸŋ ŊŸŋ 2.916 ǿżǺȮǺ VS

øøøøø

MAGNESII OXIDUM

Magnesium oxide !ǊǏȐǏǲƩDZǁ ǫǏƨǀǵ

Light ƪǏƧǪǁ !ǊǏȐǏǲƩDZǁ ǫǏƨǀǵ

Heavy ǜǏƅǁ !ǊǏȐǏǲƩDZǁ ǫǏƨǀǵ

MgO :**Molecular formula** ǦǢǺǺÂƨǟ Ǧ8ǢȎǟ

40.30 :**R elative molecular mass** ǦǢÊǺǟ ǦǢǺǺÂƨǟ ǦŸǪȮǟ

Magnesium oxide; CAS Reg. No. 1309-48-4.:**Chemical name** ɄǝǢŁǢȮǟ ǈèɍǟ

Ž ÛɄŸǪȭ ȰȮȊǟ ȤǢǺʅǟ ÿȥǺǺǢ8ţǟ ǢǢÊȭǚ ǢDZȥǺ ǛǦǶǟǚǟ ƇǢʒ ÛȐǢǛ ɉȥŸǟ ȧȥǶÊŋ :**Description** Ȥȍȥǟ
.ȤǪȭ ȧȥǶÊŋ ȰȮȊǟ ȰǢȰǪǟ ÿȥǺǺǢ8ţǟ ǢǢÊȭǚ ǢDZȥǺ Ƙǵ

.ǦǺǺǺţǟ ȏǺþɉǟ Ž ǟǟşǢ ǛTS (ȯ/ȟ750~) ȯȥǪǺǪǺǟ Ž ɍş ǿȂţǟ Ž ǢǢŸŁʒ ǟǟşǢ Ƙȡ :**Solubility** ǦǢǪǟşǿǟ
.Ǧȑȥŧǚǵ ǻǺȒŋ :**Category** ǦǺǚǟ

[illegible] :**Storage** [illegible].

[illegible] :**Labelling** [illegible].

REQUIREMENTS [illegible]

[illegible] :**General requirement** [illegible] 98.0% [illegible] 100.5% [illegible] MgO [illegible] ignited.

:**Identity tests** [illegible]

A: [illegible] 10 [illegible] 1.0 [illegible] (~70 [illegible]) TS [illegible] 1.0 [illegible] (~100 [illegible]) TS [illegible] 0.5 [illegible] (~100 [illegible]) TS [illegible] 1.0 [illegible] (~100 [illegible]) TS [illegible] (~300 [illegible]) TS.

B: [illegible] 10 [illegible] 1.0 [illegible] (~70 [illegible]) TS [illegible] 2.0 [illegible] (~80 [illegible]) TS [illegible] (~80 [illegible]) TS [illegible] TS [illegible].

[illegible] (**Heavy metals** [illegible]) [illegible] 5.0 [illegible] 70 [illegible] (~300 [illegible]) TS [illegible] 30 [illegible] 2 [illegible] 100 [illegible] (~120 [illegible]) TS. [illegible] ignited [illegible] porosity [illegible] 20 [illegible] 15 [illegible] (~250 [illegible]) TS [illegible] 25 [illegible] R [illegible] 2 [illegible] 1 [illegible] (~300 [illegible]) TS [illegible] 40 [illegible] "Limit test for heavy metals [illegible]" [illegible] A (128 [illegible] 1 [illegible]) [illegible] 40 [illegible].

Arsenic [illegible]: [illegible] 3.3 [illegible] 20 [illegible] (~100 [illegible]) TS [illegible] 35 [illegible] "Limit test for arsenic [illegible]" [illegible] (130 [illegible] 1 [illegible]) [illegible] 3 [illegible].

Barium [illegible]: [illegible] 0.10 [illegible] (~250 [illegible]) TS [illegible] 20

.ĘəÀęấ 10 ȯŸǹ ĞæÀèƅ ĞÀÜ ǰQÀǩɝ ÜŋȐƸȘ .TS (ȯ/ȟ100~) ȬÀǿźÀŸÊöä Ȑƥ ȡŋ Ȫŋ 0.10 ȣÀȒÀ .ŏÀŋ Ȫŋ

Ȫŋ 150 БÜ ĞŸĿÕǯöä (ğäÀŸÀöä) ȷấÀȟƫä ȪDZɉ ǿÀGQǹɼä ȡŋ ĞΘÀÀöä Ğǵ Àї Àöä ȡŋ Ȫŋ 1.3 ȤÀƸ :**calcium** ȳźĿÊöÀÒöä .ŏÀƫÀæ

ȡŋ Ȫŋ 0.8 ǿäÆȪŋ TS (Ca Ȫŋ/ȳäÀȡȿÀÒŋ 100) ȳźÊöÀÒŸö Ƃźφǯ ÀɋäɃǿÀĿȟƫä ȯźŸǂä ȡŋ Ȫŋ 0.20 БÜ ȣÀȒÀ

Ȫŋ 15ȿ TS (ȯ/ȟ120~) ȬĿQĿèɉä Ȑƥ ȡŋ Ȫŋ 1 ȣÀȒÀ ĞȪĿęấ 1 ÆȟæȘ .TS (ȯ/ȟ50) ȳźĿQźŋɉä ğɼÀÊȭÀÜ ȯźŸȚ .ÀÀφÜ ǵÀȒǂä ĞÀÀǺƫä Ğǵ Àї Àöä ȡŋ

(Ca Ȫŋ/ȳäÀȡȿÀÒŋ 10) ȳźĿÊöÀÒŸö ɃǿÀĿȟƫä ȯźŸǂä ȡŋ Ȫŋ 10 ȡŋ ǰÀÂŋ ȳäÆǺQèÀæ ɃǿÀĿȟŋ ȯźŸȚ ĞŏÀÎƫÀæ ÀȒȜ ȯźŸǂä Ž ɄøQöä ȬŸǩ ȡŋ ÀǯȭÜ ÀőÆї ȷźÒǩ ȡö ǿÀGQǹɼä ȯźŸȚ Ž ǰQÀǩ ȳźƫȡ ĞÀÜ ȷüź ĞȪĿęấ 15 ÆȟæȘ .ŏÀŋ Ȫŋ 5ȿ TS .(ȟ/ŊŸŋ 15) ɃǿÀĿȟƫä

.ŏÀƫÀæ Ȫŋ 10 БÜ ȤÀƸȘ TS (ȯ/ȟ70~) ȬÀǿźŸȭȿǿÆĿȚä Ȑƥ ȡŋ Ȫŋ 5 Ž ȟ0.15 ǟäØÀ :**Iron** ÆÀÆΣä ȪDZɉ ɃÆΣä ǿÀGQǹɼä" ȷäźÀȜ ǨƠ ȣźòźŋ źȽÀŋ ÆÊШ ĞΘÀÀöä Ğǵ Àї Àöä ȡŋ Ȫŋ 4.0 ɁŸȜ ȪƭȟÖä ȪƭÒQÊÀ .ȟ/ȳäÀȡȿÀÒŋ 500 ȡȜ ÆÀÂÀ ɼ Ü(129 ĞĦÀÔöä Û1 ÆŸÕä) "Limit test for heavy iron ÆÀÆΣä

ĜїÀÀ .ĘəÀęấ 5 ǵÆŋ ɁŸȣÀȘ ŏÀŋ Ȫŋ 100 Ȝŋ ȟ2.0 ǯÂƸ :**water-soluble substances** ŏÀƫä Ž ĞæäȿǾöä ấäźƫä ȡŋ Ȫŋ 50 ÀÀǺǂ .ŏÀƫÀæ Ȫŋ 100 БÜ ȤÀƸȘ ÛấƎĿö ȭÀQÀ ÛȡÎʅä ÀĐźǂä ǯÀDZÂöä Ğǖ ÀȟȜ ǿÀǵ ŏÀƫä ȷźÒÀ ÀƭÀĿæ .ŊŸŋ 20 ȡȜ ĞöÀƭǯöä ȷäȘ ÆÀÂÀ ɼ ÜǨæÀǯöä ȷäźöä ɁøQǵ °ȳ 105 ĞDZǿÆöÀæ ȤÀƶȘ ȣÀƨä ɁøQǵ Ğǵ Àї Àöä

ɁŸȜ ĞĿȪQQƫä ÛĞöÀƭǯöä ȷäȘ ÆÀÂÀ ɼ :**substances insoluble in acetic acid** ȬĿQĿèɉä Ȑƥ Ž ĞæäȿæŸöä ấäźƫä ȤÀΘȘ ŏÀƫÀæ ȪÊȣɫ ÀŋÆÀȜ ÛĞŸĿȪǯöä ȷấÀȟƫä ȪDZɉ ɃÆΣä ǿÀGQǹɼä Ž ȮĦÀŸö ǿĿȟƫä ȯźŸǂä ǨȒƠ Ž ȳÆǺQÊƫä ĞǖÀƫä .ŊŸŋ 5 ȡȜ Û°ȳ 600 ĞDZǿÆöÀæ ÆȚŸǩȘ

ȡŋ ÀǯȭÜ ÆȪÀÀ ɼ ÜǨæÀǯöä ȷäźöä ɁøQǵ°ȳ 900 ĞDZǿÆöÀæ ȟ1.0 (ÆȚŸɫ) ÆŋÀɫ :**loss on ignition** ȯÀȟQїɼÀæ ÆȪÀöä .ȟ/ŊŸŋ 100

TS (ȯ/ȟ70~) ȬÀǿźŸȭȿǿÆĿȚä Ȑƥ ȡŋ Ȫŋ 20 Ž ÛĞĿüźĞȒŋ ĞφȿäźŋÛȟ 0.35 ĞæäÀę ǟäØɫ :**Assay** ĞÊÀÀȪƫä Complexometric ğäÆȪȟƫä ǡÀĿȪŋ ğäÀÀȟƫä" ȷäźÀȜ ǨƠ ȣźòźŋ źȽÀŋ Àŋ ÆÊШ ǵÀÀȟƫÀæ ȪƭȟÖä ȜÀƶȘ (ȯ/ȯźŋ 0.05) ȳźÀấźÔöä ĞĿəÀÀφ ğÀQÀÆÀÜ ȯźŸȚ ȡŋ Ȫŋ 1 Ȫȭ .(138 ĞĦÀÔöä Û1 ÆŸÕä) ȳźÀÀĿȣƫä ȪDZɉ "titrations .MgO ȡŋ ŊŸŋ 2.015 ŏżÀÒÀ VS

ØØØØØ

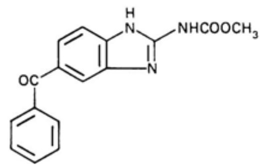
MEBENDAZOLUM

Mependazol üNjȐƐɷďƗĜĨĎŽ

$C_{16}H_{13}N_3O_3$ **:Molecular formula** ĞĘǺÂƨǟ Ğ8ĘÔöä

295.3 **:R elative molecular mass** ĞĘĜÊÀöä ĞĘǺÂƨǟ ĞŸǪỎöä

:Graphic formula ĞĘɸǺĘĜţä Ğ8ĘÔöä



:Chemical name ɄəǺĘŧĘỎöä ḻèɍä

Methyl 5-benzoyl-2-benzimidazolecarbamate; methyl (5-benzoyl-1*H*-benzimidazol-2-yl)carbamate; CAS Reg. No. 31431-39-7.

.ⱫĘǺǹ ȀÀòǕ БǕ ȒĘǽǕ ȷⱬŸǽ àⱬĦÊɳ **:Description** Ɀòⱬöä

Žɍş TS (ȯ/ȟ750~) ȯⱬɸǺǯǺqä Ž ɍş ĞĘɸÆȞţä ôǺþɉä Žɍş ǒǺţä Ž ĦĘŸŧ3 āäşǽ Ƙɖ **:Solubility** ĞĘɸǺǽşØöä

.TS (ȯ/ȟ1080~) ŌĘɳøⱬÀöä Ȑþ Ž ȷǺǽşØöä Ǻǵ ÜR ÿøⱬⱬşøⱬŸỎöä Žɍş Ƙǭɉä

.ȷäÆǺÆŸö ǻøǺü ǒäşǻ **:Category** ĞǺÀöä

.ǒⱬȒöä ȡɳ ĞĘŧƬ ÛĦÆĘĎƵ ĞŌŸ8ɳ ĜǺşǺǵ Ž ȯşȁäÆĘÆĜĘţä ȘǺǵ Æƶ **:Storage** ȡÂÂǺǪöä

REQUIREMENTS ƘĜĥŭŎƘŽ!ƒ

%102.0 ȡ3 āşØǩ ɍ %98.0 ȡ3 ŌǾǺ ɍ Ǻɳ ʔŸ3 ȯşȁäÆĘÆĜĘţä Ƀⱬǫ3 **:General requirement** ÿǺȞöä ÆŸÛǪţä

.ĞǺÀÕä ǥǻǺţä БǕ ţⱬĎȀöǺǽ ĜǽⱬÊƬ Û$C_{16}H_{13}N_3O_3$ ȡɳ

:Identity tests ƕĬNjNJƐ lƐþƑĜƗƢƐ

• ȡÒⱬ ĘĜÛǩ Ǻɳ ǕŦȁŤöä A ȁǺÀɳ ȼǻǺȀöäɳ B ȡǺøǺĜǪǹɍä şǕ .Cş

A: ĘĜÛǺ ȌĦǺöä ȚȁǺ 8ⱬòⱬɳ ⱬŁ ǺŧŌ ǮȝȀö ȷäⱬǺ3 "ǽǺĘǻâ ȹĘÛöä ɄəⱬȒöä Ž ĞŌÛǺɳ ĞĤìɉä ȚȁǺ ǒäǺŧΣä

ȚȁǺ ĞĤìɉä Ž îǺÔǪɳɍä ȹĘü ĘǽǺÛǪǺ .(43 ĞȞǺÔöä Û1 ÆŸÕä) "Spectrophotometry in the infrared region

.ȯşȁäÆĘÆĜĘŧŸö *refernce spectrum* ɄȞĎȀţä ȹĘÛöä 3ɳ şǕ RS ȯşȁäÆĘÆĜĘţä ȡɳ ǰǨǺöä ȹĘÛöä 3ɳ ǒäǺŧΣä

B: ǶȒƸ 20 ŊŸɳ 3ɳ 2.0 Ōɳ ȡɳ ȯⱬŸƬ ÆĘÊŌşøÆĘŁ ÿⱬǺǻⱬÔöä ÛTS (ȯ/ȟ80~) ȡǺÊǺş ĘŸȞǪÊţä ȷⱬŸţä ȷⱬŸǽ

[illegible] (ò/ȟ100~) [illegible] (ò/ȟ160) (II) [illegible]

[illegible] (ò/ȟ1760~) [illegible] 2 [illegible] 20 [illegible] :C [illegible] (ò/ȟ 40) [illegible] 1.0 [illegible] 3 [illegible] .TS (ò/ȟ100~) [illegible]

[illegible] ȟ1.0 [illegible] :**Heavy metals** [illegible] 3 [illegible] "Limit test for heavy metals [illegible] (128 [illegible] 1 [illegible]) A [illegible] (127 [illegible] 20 [illegible] .ȟ/[illegible] 1.0 [illegible] :**Sulfated ash** [illegible]

[illegible] 0.6 [illegible] 105 [illegible] :**Loss on drying** [illegible] .ȟ/[illegible] 5.0 [illegible] 4 [illegible] 5 [illegible]

[illegible] :**Related substances** [illegible] R6 [illegible] (84 [illegible] 1 [illegible]) "Thin-layer chromatography 5[illegible] R [illegible] 5 [illegible] 90 [illegible] 10 [illegible] TS (ò/ȟ1080~) [illegible] 1.0 [illegible] 50 [illegible] :(A) [illegible] R [illegible] 10 [illegible] TS (ò/ȟ1080~) [illegible] 1[illegible] R [illegible] 9 [illegible] 200 [illegible] A [illegible] 1.0 [illegible] :(B) [illegible] .TS (ò/ȟ1080~) [illegible] A [illegible] 254) [illegible] .B [illegible]

[illegible] R1 [illegible] 30 [illegible] 0.22 [illegible] :**Assay** [illegible] VS (ò/[illegible] 0.1) [illegible] 1 [illegible] .(142 [illegible] 1 [illegible]) A [illegible] " Non-aqueous titration [illegible] 29.53 [illegible] VS (ò/[illegible] 0.1) .$C_{16}H_{13}N_3O_3$

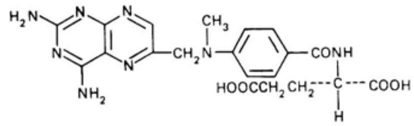
METHOTREXATUM

Methortrexate ƖƑƨƞƥƗǋǨǏǅ

$C_{20}H_{22}N_8O_5$ **:Molecular formula** ǦƎǠǺƨǞ Ǧ8ƎÔǚǟ

454.4 **:Relative molecular mass** ǦƎƓÊǺǚǟ ǦƎǠǺƨǞ ǦŸǪȮǚǟ

:Graphic formula ǦƎǫǠƎƓţǟ Ǧ8ƎÔǚǟ



:Chemical name ȖǝǠƎŧƎȮǚǟ ǇèƑǟ

(+)-*N*-[*p*-[[(2,4-Diamino-6-pteridinyl)methyl]methylamino] benzoyl]-L-glutamic acid; *N*-[4-[[(2,4-diamino-6-pteridinyl)methyl]methyl-amino]benzoyl]-L-glutamic acid; CAS Reg. No. 59-05-2.

.ƃǠǑǨǺǣ ƃǕ ǺǺòǕ ɈƺŸǣ ȸøƺŸǣ ȧƺƕÊŋ **:Description** Ƶòƺǚǟ

Ž ƑȘ R ɈǠǮǕ øƺŸȮǺƝǚǟ Ž ƑȘ TS (ȯ/ȟ750~) ȯƺǫǠǮǺɋǟ ŽƑȘ ǒǠţǟ Ž ƝƎŸŧ3 ǡǟȘǣ Ƙȡ **:Solubility** ǦƎǫǠǣȘǾǚǟ

.ǧǠǫƺǣǺȮǚǟȘ ǦǺƺŸǑǚǟ ǧǟƝƎÊǬȘøƝƎƮŸǚ ǦǺǻǺŢǟ ǑƎǠǂǟ Ž ƝƎǄ ǡǟȘǣ ÜR Ƙǭɉǟ

.ǺǺŸǺŸǚ ŷǠè ǒǟȘǻ **:Category** ǦǠǺǚǟ

.ǒƺȒǚǟ ȸȠ ǦƎŧƮ ÛŷǠȮǵǘǟ ǦǑŸ8ȠȠ ǦǺȘǠǵ Ž ǧǠÊȮǺǺǨƺǮƎţǟ ȘǠǵ Ǽƶ **:Storage** ȸǺÂǺǪǚǟ

øØ∑ǟ Ȗǹƺǩ Ǽƶ :ǺǺØƠ .ƝƶøǺǨ ǒƺȒǠǣ ǧǠÊȮǺǺǨƺǮƎţǟ ǺǪǟǪǨ **:Additional information** ǦƎƺǠȑǕ ǧǠŋƺŸǪŋ

.ǒǚƺƬǠǣ ǦǚƺǑǺţǟ ǧǠŧƎÊƨǟ ȧǠÎǺǪèǟȘ ƝŸƨǠǣ ǡǠŧǪǚǟ ƝǺƟȘ ȸƝǺɉǠǣ ǧǠÊȮǺǺǨƺǮƎţǟ ǦŸŋǠǶŋ ƝǺ3 ǦǺǺǶǚǟȘ

REQUIREMENTS ƘǦǕǚƱǨǨǃ!ƒ

ȸ3 ǡǟȘǾǨ Ƒ %96.0 ȸ3 ǑǑǺ Ƒ ǺŋʔŸ3 ǧǠÊȮǺǺǨƺǮƎţǟ ȸƺǪ3 **:General requirement** ŷǠǶǚǟ ƝŸÛǪţǟ

.ǦƎǝǠŋŸǚǟ ǥǠţǟ ƃǕ ţƺǄǺǚǠǣ ǦǣƺÊƮ Û$C_{20}H_{22}N_8O_5$ ȸŋ %102.0

:Identity tests ƕǏǋǈǁƐ ƖƐƥƑǴƏƮƐ

ǨƠ ǦǶǏɉǟ ǦǑÛǺŋ Ž ȖǝƺȒǚǟ ƵƎÛǚǟ ǡǠƎȩ" ɈǣƺǺ3 ǨƠ 8ƺòƺŋ ƺŁ ǠŧǬ ÒƕǠǚǟ ȨƓÛǺ :A

ǦǶǏɉǟ Ž ȋǠÔǪŋƑǟ ƵƎù ȨǣǠÛǪǺ .(43 ǦƕǠÔǚǟ Û1 ƝŸǑǟ) "Spectrophotometry in the infrared region"ǚǺŧ∑ǟ

.ǧǠÊȮǺǺǨƺǮƎŧŸǚ *refernce spectrum* ȖǶǄǺţǟ ƵƎÛǚǟ 3ŋ ȘǕ RS ǧǠÊȮǺǺǨƺǮƎţǟ ȸŋ ǰǨǺǚǟ ƵƎÛǚǟ 3ŋ ǒǚǺŧ∑ǟ ǨƠ

(ọ/ọǫ 0.1) ÿǫǻǫÔöä ÆÊõşøÆŁ ọǫŸŢ Ž Ōŋ/ÿäǿşÀÒŋ 10.0 ÂÆõÀǪ ọǫŸǂ î ÅÔǪŋɼä ǫÆù ɃÆĜ :B ĞäÀę ǯäǫŋɉä ọäǫüüæ ĞÆŧŢʒÜ ğÅòÅÔǪŋä 3 ÛÀǪŋǫǿǿ 380ş ÀǪŋǫǿǿ 230 ƙæ ǯäǫŋɉä ọäǫüÜ Ž ÆŁÅÎ ÅŋÆʒ ÛVS 2.8 ƙæ ÀǪŋǫǿǿ 371 ĞDZǫţÅæ ɃØöä Ōöæ БÜ ÀǪŋǫǿǿ 303 ĞDZǫţÅæ î ÅŧǪöä ĞĜÊǿ ɉǫÒǩş.ÀǪŋǫǿǿ 371ş Û303 Û258 .3.3ş

ÿǫǻǫÔöä ğÅǿǫäÀõ ọǫŸŢ ȸŋ Ōŋ 12 Ž ȟ0.25 āäØ :**Specific optical rotation** Ʉʒǫöä ɃÀÔĜöä ÀşÆǪöä

$.[a]_{\mathrm{D}}^{20^{\circ}\mathrm{C}} = +19 \text{ to } +24^{\circ}$ ÜĞÆǝÅŋŸöä ģǻţä БÜ ţǫDZÀöÅæ ĞDzÆǪöä ÆÊȞǩş ÛŌŋ 25 БÜ ŏÅţÅæ ǫÅƩ ÛTS (ọ/ȟ10)

.ȟ/ŊŸŋ 1.0 ȸʒ ÆÂ ɼ :**Sulfated ash** ǨÅŸÊţä ǻÅŋÀöä

Determination of water by ÀÎÆǫ ọøÅõ ĞŌÀÛæ ŏÅţä ƙÆǩ" ɉäǫʒ ǨƠ Ȣǫòǫŋ ǫŁ Åŧõ ȸÆǨ :**Water** ŏÅţä ŏÅţä Ɂǫ ǪŢ ÆÂ ɼ ÜģÅţä ȸŋ ȟ 0.5 ÿäÆǺǪèÅæ Û(145 ĞȞÅÔöä Û1 ÆŸŎä) A ĞŌÀÛöä Û"the Karl Fischer method

.ȟ/ŊŸŋ 120 ȸʒ

.packing material ģǫÎƩä ģÅŧõ A ÀŌǪÊţä øǫÛöä ŌŧȞǪÊ :**Assay** ĞÊÀŌţä

ɉäǫʒ ǨƠ 1 ÆŸŎä ɁŸʒ ĞÆŸŧÒǪöä ğŸÆȞöä Ž 377-373 ƙæ ğÅȞÅÔöä Ž Ȣǫòǫŋ ǫŁ Åŧõ øÅĜǪǹɼä ĘĜÛ ʖè 10 ọǫü Ƀæ ǻǫţʒ ÿäÆǺǪèÅæ Ûhigh performance liquid chromatography àÅƠqä ʒÆǫÀöä ŌǝÅÊöä āäÀÎǪèɼä ʒŋ ɄǝÅÆŧÒöä ɼÅĜǩøɼÅæ ǴÛÊöä ÅŢÆǫ ọÆɮ ɄøǪöäş ÛÀǪŋşÀÒŋ 5 ÀÛŌæ ÛÀÒÆŸÆÊöä ĞŋŸŏ ǫÎŢ ʖŸŋ 6 ɄŸǹäǻ ÀÛęş

.octadecyl silyl groups ğÅʒǫŧƒ

ğäÀǪÆè/ğÅÀÊǁ ĞǝäøǻȸŋÅŧDzǵ 92 ʒŋ R ŌÀÀǪǫǪÆèɉä ȸŋ ÿǫDzǵ 8 ȸŋ ǰÂŋ ÿÆǺǪÊ ÛõÀȞǪţä øǫÛŸö ĜĜÊÀöÅæ

.TS Û6.0 ŏÅŁÅæ ğäæ

Ōõ Ž øÅĜǪǹɼä ģÅŋ ȸŋ ŊŸŋ 0.10 Ƀǫʒ :(A) ọǫŸǂä ÛǨÅǿÜ øǫõØţä õÀȞǪţä øǫÛöä ọǫŸŢ Ž ĞÆŏÅǪöä ŌÆŏÅǂä ÀȐƠ ȸŋ ŊŸŋ 0.10 Ƀǫʒ :(C) ọǫŸǂäş ÛŌŋ 1 Ōõ Ž RS ğÅÊƉÀǩǫǯÆţä ȸŋ ŊŸŋ 0.10 Ƀǫʒ :(B) ọǫŸǂä ÛŌŋ 1

.äÅŢƨä ĞȟǿŸȟ øÅĜǪǹä ŌDzɉ Ōŋ 1 Ōõ Ž RS ŌÆöǫÀöä Ȓþ ȸŋ ŊŸŋ 0.10ş RS ğÅÊƉÀǩǫǯÆţä

âÅÆŌŋ ȢÅÎÒŧõ ÿÆǺǪÊş .ĞŌÆęǻ 1 Ōõ Ž Ōŋ 1.4 ĞäÀę ĘǫÆǩ ĞʒÀÊæ ĞǫÀȢöä ģøäÀǵ ĞDzøǻ Ž ŌŧȞöä ɁÀƶ ȒÅǺÅŋ ʖDzǵ ğäæ ĘǫÆǩ ģǨDzɰ ǼǿşÂŋ ÛÀǪŋǫǿǿ 303 ĞäÀę ĞDzǫŋ ọǫÛæ ĞÆDzÊÀĜöä ȧǫǫ ĞȞÌɉä Ž ɄǝǫȒöä ǫÆÛöä .ÆèÅŋ ŌþDzÊŋş Û(ĞŧǝŸŋ ÀǪöşÀÒŋ 10 ʖDzƩä ğäæ ģǨDzƩä ÆȞǩ)

ƙæ resolution factor ÂÆţä ŌŋÅʒ ɉǫÒÂɼ ɉÜ Æƶ .ÀǪöşÀÒŋ 20 ÅŢÂŋ Ōõ ÛC ọǫŸȞŧŸö ĞÅʒÅȒŋ ȸǵ 6 ɁÀɵ peak ģşøØö relative standard deviation ɄøĜÊǿ ɃøÅÆȞŋ ȢäÀÛä ʒŋ Û5.0 ȸŋ Ōęܘ ŌÆöǫÀöä Ȓþş ğÅÊƉÀǩǫǯÆţä

.(ĘæÅÛǪöä ǪÆʒ B äæÜ õÀȞǪţä øǫÛöä ĜĜÊǿş ĘǫÆǪöä ĞʒÀè ọÆȞǨ) %2.5 ȸʒ ÆÂ ɼ ğÅÊƉÀǩǫǯÆţä

ǼøÆŌŋ ɁǫǪǂä ÆÊʒş peak responses ɁøØöä ğÅæÅDzǪèä âÅŌǩ .Bş A ƙọǫŸǂä ȸŋ Ōõ ȸŋ ÀǪöşÀÒŋ 20 ȸŌʒ

[illegible] (%) [illegible]: $C_{20}H_{22}N_8O_5$ [illegible]: $100(A_1 M_2 T) / (A_2 M_1)$.

[illegible] A_1 [illegible] A_2 [illegible] M_1 [illegible] M_2 [illegible] T [illegible] purity [illegible] RS.

[illegible]

Additional requirement for Methotrexate for parenteral use

[illegible] "*parenteral preparation*" [illegible] (56 [illegible]).

[illegible]

METHYLTHIONINII CHLORIDUM

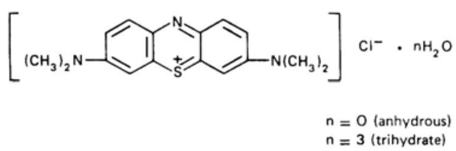
Methylthioninium chloride [illegible]

[illegible] **Molecular formula:**

$C_{16}H_{18}ClN_3S$ (anhydrous) [illegible] $C_{16}H_{18}ClN_3S, 3H_2O$ (trihydrate) [illegible].

[illegible] **Relative molecular mass:** 319.9 (anhydrous); 373.9 (trihydrate)

[illegible] **Graphic formula:**



[illegible] **Chemical name:**

C.I. Basic Blue 9; 3,7-bis(dimethylamino)phenothiazin-5-ium chloride; CAS Reg. No. 61-73-4 (anhydrous).
C.I. Basic Blue 9 trihydrate; 3,7-bis(dimethylamino)phenothiazin-5-ium chloride trihydrate; CAS Reg. No. 7220-79-3 (trihydrate).

[illegible] **Other name:** [illegible] Methylene blue.

[illegible] **Description:** [illegible]

[illegible] **Solubility:** [illegible] (~750) [illegible] TS [illegible] R [illegible] R.

.Antidote ȧÅǾǻ :**Category** ĞÂÀőā

.őζȒőā ȸɳ ĞȄȶŢ ÛÿǺÒǵüǣ ĞǑŸ8ɳ ĞȦşǺǵ Ž ÿζȄÆɸζȄɸ ŌȄǯȄţā ÆȦøζŸÕ ȘǺǵ Æƶ :**Storage** ȸȦÂǺǪőā

.hygroscopic ĞĜùǺǪÊɳ ǵǻÅɳ ÿζȄÆɸζȄɸ ŌȄǯȄţā ÆȦøζŸÕ ÆĔĦ :**Additional information** ĞȄζǺȓŬ ğǺɳζŸĦɳ

REQUIREMENTS ƘĞŝÛƱkāž!ƒ

ȸȝ ÆȦÂȦ ɍş %97.0 ȸȝ ŌŌȦ ɍ Ǻɳ ʔŸȝ ÿζȄÆɸζȄɸ ŌȄǯȄţā ÆȦøζŸÕ ɃζǪȜ :**General requirement** ÿǺĦőā ÆŸÛǪţā

.ĞÂǺŎā ǵǻÅţā ƂŬ ţζDZǺőǺǣ ĞǣζÊŢ Û$C_{16}H_{18}ClN_3S$ ȸɳ %101.0

:**Identity tests** ħǐŇǌǈǁ Ɩ ƐƥƑĠƗǈƐ

ǺɳÆȦȝ ÛTS (ȯ/ȟ70~) ŌȦøζŸÕşøÆȄTā ȐƥŽ Ōɳ/ÿāǺɖşǺÒɳ 5 ÂȄÕǺǪǣ ȯζŸɨ ȋǺÔǪɳɍā ƵȄù ɃÆĜȦ :A

.ǺǪɳζɸǺɸ 745ş Û680 Û288 Û258 ĞāǺę ĞȄȶŢȝŬ ğǺòǺÔǪɳā 4 ǺǪɳζɸǺɸ 800ş ǺǪɳζɸǺɸ 230 ƙǣ ÆȽǺȊȦ

ŌȦøζŸÕşøÆȄTā ȐƥȸɳŌɳ 2.0 ȣǺȒȦ .ȨǝǺɖ ȧøàŬ ɉζǐ ǰǪȦȦ ÜőǺţā ȸɳ Ōɳ 10 Ž ȠŸɳ 1 āāØȦ :B

ɉζŸőā ǻζĦȦ ÜőāζTā ƂŬ ĞǵǺȉǺőā ȏǺĦǩş ǴȉǺȦ ÜȯζŸɨā ɉζǐ ʔȉŸǪȦ ÜR ŌɸÂőā ȧζĦÊɳ ȸɳ ȟ 0.25ş TS (ȯ/ȟ70~)

.ÆȦÆDZ ȸɳ øζŦŢŸő ȧøàɉā

ĞDZøÆő øØɰ ǰȦÂţā ȸǺÊȦ .ȣÂɿā ȸɳ ĞŌǩζǣ Ž R ĞȄǝǺɳŸőā ÿζȦǻζÔőā ğǺɳζǣǺÕ ȸɳ ȟ 0.5 ȝɳ ȟ 0.05 ǯÂƺ :C

ɄÛĦǩ .ǴȉǺȦş TS (ȯ/ȟ130~) ŌǺǪőā ȐƥȸɳŌɳ 10 Ž ĞȄŌĜőā āāØɫ ÛǻƎȦ .ȨǝǺę ǻ 10 ǵÆɳ ǺƥɉāǰȽζǪőā

ŌȝǺǪÕ "General identification tests ĞɳǺĦőā ȣāǺĦǪèɍā ğāøǺĜǪǹā" ɉāζȝ ǨƠ ȣζòζţā A ŌȝǺǪőā ĞǵǺȉǺőā

.(121 ĞĦǺÔőā Û1 ÆŸÕā) ğāÆȦøζŸÒŸő Âȶȶɳ

ǵøāǺǵ ĞDZøǻ ÿāÆǺǪèǺǣ ȣÂɿā ȸɳ ĞŌǩζǣ Ž ȟ1.0 (ŌĦÎɫ) ÆȄŸȦ :**Copper and Zinc** ŌɸÂőāş âǺĦőā

(ȯ/ȟ130~) ŌǺǪőā ȐƥȸɳŌɳ 15 ȣǺȒȦ ÛĞǺȶǯőā ǻƎǩ .ɉζǣǺÒőā ŌɳǺÕ ÆÊÕüǪȦ ʔøǪǵ ÛţǺÛǪÊȦ Ǻɳ ȐǺǹüǣ

200 őżǺÒǩ ÛR (II) âǺĦőā ğǺǺŸè ȸɳ ĞȄȶÕ ƙǺÊǪǣ ɄĦDZǺɳ ȯζŸŢ ȾŸÔǺǺɳ ǺȒȝ .ȨǝǺę 5 ǵÆɳ ʔŸ8ȦşTS

øǺǪǪǹɍā ȯζŸŢ ȾŸÔǺǺɳ ǴȉǺȦ .ȨǝǺę 5 ǵÆɳ TS (ȯ/ȟ130~) ŌǺǪőā ȐƥȸɳŌɳ 15 ȝɳ ÛCu ȸɳ ÿāǺɖşǺÒɳ

ŌőØÕş øǺǪǪǹɍā ȯζŸŢ ğɍζÊɖş ĞǵǺȉǺőā ȝȶƟ .őǺţā ȸɳ Ōɳ 10 øāÆŌɳ ĞǺȶȽ ĞŬ ŌÊ8ǩş ÛȸȦǻƎţā ɄĦDZǺţā ȯζŸɨāş

ǴȉǺȦş TS (ȯ/ȟ100~) ǺȄɸζɳɉā ȸɳ ǵǺȦā ǺȶȽǺɳ ŌÕ ƂŬ ȣǺȒȦ ÜɄĦDZǺţā ȯζŸɨā ğɍζÊɖş ĞǵǺȉǺőā ȝȶƟ

ÛőǺţā ȸɳ ǵƘ8ò ğǺȄȶÒǣ ĞǣǺèƅ ŌÕ ŌÊ8ǩ .ȄȶDzǵ ĞDZøÆɳ Ōɳ 50 ǱDzɰ ĞŸDZζǵ ŌǹāǻƂŬ ǺȶȽǺɳ ŌÕ ɉɍζŸɨā

ȸɳ Ōɳ 25 ƂŬ ȣǺȒȦ .ǯÂƺş ÛǱDzƩā ʔøǪǵ őǺţǺǣ ĞŸDZζǵ ŌÕ ʔζǪŢ ƵǺƩ ÜĞǵǺȉǺø ŌÕ ƂŬ ğɍǺÊȸőā ȣǺȒǩş

ȨǝǺę 5 ǵÆɳ ȯŸǹ ǺÒȝ ɃŬ ǰǪȦɍ Ühydrogen sulfide TS ƙDZşøÆȄTā ÆȄǺŸè ȯζŸŢ ȸɳ Ōɳ 10 ƙȯζŸɨā ȸɳ ŌÕ

ɄĦDZǺţā ȯζŸɨā Ž ɃØőā ŌȯǣȸɳǵÆȉ ǺǯÕŬ øǺǪǪǹɍā ȯζŸŢ Ž ŌÒÎǪȦ ȸÕǻ ɉζǐ ɃŬ ɉζÒȦ ɍş (ŌɸÂőā āǺȄɖ)

.(ȟ/ƞŸƞ 0.20 ȸȝ âÅĦƲÁöä ʔɀϘƮ ÆÂÂɍ)

Ȑƥ ȸƞ Ōƞ 15 ȣÅȒ ÛĜŸɀù ĞǤǿş ǿşÆƞ ÂĦȩ ğäæ ĞŸǱɀǵ Ž ŏÅƞ Ōƞ 200 ȝƞ ȟ 4 ǯÂɛ :**Iron** ÆÂÆΣä
БäɀǵБÛŌǝÅÊöäǈǱǵȐÅǺ ʡøϘǵ ɈÅŸȣöÅæ ÂȶϘÊÂş ɈÅŸȣöä ʡøϘǵ ȤÛŸæ ȸǺÊÂş ÛTS (ȯ/ȟ1000~) ŌÅÂϘÂöä
ɈÅŸȣöä ʡøϘǵ ȸǺÊÂ .ǯÂɛş TS (ȯ/ȟ1760~) ŌÂǿɀÅŸÊöä Ȑƥ ȸƞ Ōƞ 10 ȣÅȒÂş ÛåƎö ȭÅϘÂ .Ōƞ 20
ʡŸȝ ȯɀÔΣä ʡøϘǵ ÛĜɀÅȑÛ Ōȭ ŌǤȩ åƎÂ ÛTS (ȯ/ȟ1000~) ŌÅÂϘÂöä Ȑƥ ȸƞ ĞƎöÅϘϘƞ ǥƘȣö ğÅƎȶȭ ȣÅȒƚş
ȐȶɰĞƨÅĦţÅæ ÂȶϘÊƚ ĞŸǵÅţä ȻØȽ Ž ȸȭäåɈɀö ÂȚş äæÛ ÛȐƎæÛ ɈɀŸæ ȸǝÅȵå ǿɀÛϘǩ ʡøϘǵ ȸǺÊÂ .ɈɀöɈşå ŌǝÅè
ÛåƎö ɈɀŸöä ȻÆȝ ŌǝÅÊöä ȭÅϘÂ .ȐƎæÛ ɈɀŸæ ȸǝÅȵå ĞƎϙÅϘ ǿɀÛϘǩ ʡøϘǵ ȸǺÊÂ ÅƘȵÛş ÛTS (ȯ/ȟ1000~) ŌÅÂϘÂöä
ÛåƎÂ .ÅƞÅϘ ĞÂƎÂʅä ǥɀɖÅöä Æȶơ ʡøϘǵ ʡŸȣÂş ÛöÅţä Ž R ȳɀϘɀƞɉä ğɍÅÊȭÅ ȸƞ ȝĜÎƞ ȯɀŸƮ ȸƞ Ōƞ 25 ȣÅȒÂ
ǿÅĜϘȵɍä" ɈäɀÂȝ ȞƠ åǿş Åţ ǢƎǱϘÊÂ ȤÅǺţä ȯɀŸɉä ȸƞ Ōƞ 5 ǿäÆŌƞ ÅȶǱǵ ɈÛ ÜöÅţä Ž Ōƞ 50 ʡøϘǵ ȤÅƩ
.ȟ/ƞŸƞ 0.10 ȸȝ ÆÂÂ ɍ Ü(129 ĞĦƲÅÔöä Û1 ÆŸŎä) "Limit test for heavy iron ÆÂÆΣä ŌǱɉ ȻÆΣä

.ȟ/ƞŸƞ 10 ȸȝ ÆÂÂ ɍ :**Sulfated ash** ȞÅŸÊţä åÅƞÂöä

ÂǯȭÛɍş ȟ/ƞŸƞ 80 ȸƞ ŌǤÛ ÆŌÅÂ ɍ Ü°ȳ 105 ĞǱǿÆæ ȞäÅǯöä ɈàɀöäȸƞȤÅƺ :**loss on drying** ȤƎÅǱϘöÅæ ÆŌÅöä
.ȟ/ƞŸƞ 220 ȸƞ

Thin-layer ĞŌƎȩÂöä ĞŌĜÛöä āäÂÎϘèä" ɈäɀÂȝ ȞƠ ȣɀòɀţä ǿÅĜϘȵɍä ȨĜÛÂ :**dyes foreigne** ĞĜÂȣöä ȟÅĜòɉä
ĞŸǰȣƞ ǥåȶȭ R1 ÅŌƎŸƎÊöä ĞƞŸȽ ȸƞ ǥÅȒƮ slurry ĞæşǿȳäÆǺϘèÅæ Û(84 ĞĦƲÅÔöä Û1 ÆŸŎä) "chromatography
ğÅÂÊƺ ȯɀŸƮş TS (ȯ/ȟ27.2) ƘǱşǿÆƎTä ĞƎǝÅϘ ȳɀƎèÅƙɀĜöä ğÅÂÊƺ ȯɀŸƮ ȸƞ ĞÂşÅÊϘƞ ȳɀǱǵ ȸƞ ȷÂÂƞş
4 ÛR ȯɀϙÅæşÂä-1 ȸƞ ÅȶǱǵ 20 ȸƞ ȷÂÂƞ ÛȭÂĦϘƞ ǿɀÛȭ ÛŌȶƗϘÊÂş .TS (ȯ/ȟ28.4) ȳɀÂåɀÔöä ĞƎǝÅϘ ƘǱşǿÆƎȽ
ƞŸƞ 25 ĞäæÅæ ÂȒƮ ȯɀŸƮ ȸƞ ÂϘöşÂŌƞ 2 ȲÔÅÂƞ ȨĜÛÂ .ŏÅţä ȸƞ ÅȶǱǵ 1ş ÛR ȢǝÅƞŸöä ŌƎƞǿɀÅöä Ȑƥ ȸƞ ȳɀǱǵ
ǥƘǱǵ ȸƞ ĞĦƎÅÔöä ţÂφ ÆĦæ .Ōƞ 10 ǿÆŌæ ǈǱǵ ŏÅÛȝɋ R ȯɀϙÅǰƎţä ȸƞ ĞƎɀÅȭ ĞƎȶȭ Ž ǿÅĜϘȵɍä ǥåÅƞ ȸƞ
ÅȚȒĦæ ȸƞ ÅÆǱ ĞĜÂȩ Û0.5 ĞäæÂȩ *Rf* ĞȶƎȩ ÆÂȝ ȝŌæ 4-3 ÂȚȚƙ .°ȳ 105 ĞǱǿÆæ ɈÂɀ Ž ȤǱϘö ȭÅϘƙ ÛāäÂÎϘèɍä
.ȝŌĜŸö ÆȝÅÔöä ǢƎƘÂϘöÅæ ɈɀŸöä ǥÆì ååÂƙş ÛÂƥÛ ɈɀŸæ ʔÂȵɉä ȝŌĜöäş ȢǱÊÂÂæ ɈɀŸæ ƅåɉä ĞȞŌĜöä ɈɀȮƙş ÛȒĦæ
.ʔÂȵÛ ĞȞŌæ ĞÂÛ ÂȚȚƙɍş

Ōƞ 30 Ž āäØƙ ÛƎȶǱǵ ĞǱǿÆƞ Ōƞ 100 ǈǱɰ ĞŸǱɀǵ БÛ ÛĜƎùɀĜȒƞ ĞφşàɀƞÛȟ 0.3 ĞäæÂȩ ŌŌÅÂ :**Assay** ĞÊÂÅŌţä
ȳɀƎèÅƙɀĜöä ğÅƞşÂȭ ȢǝÅϘ ȯɀŸƮ ȸƞ Ōƞ 50.0 ÛȐʅä ŏÅϘÛ ÛȣÅȒÂ .åƎö ȯɀŸɉä ȭÅϘÂş ÛȢǝÅƞ ȳÅƥ Ž ƘǺÊϘöÅæ ŏÅƞ
ǳÂÛƚ ÜĜìÂÂş ÛȨǝÅȩå 10 ǥÆƞ ȝÛŌϘƞ ŌȮÎæ ƞȐʅä åÅĦÂ .ǯÂɛş ÛǈǱΣä ʡøϘǵ ŏÅţÅæ ȤÅƩ ÛVS (ȯ/ȯɀƞ 0.0167)
ȸƞ Ōƞ 40 ȣÅȒÂ ÛĞƎǱÅǱǻä ǥåÆè ğäæ ĞŸǱɀǵ БÛ ĞǵÅìÂöä ȸƞ Ōƞ 50.0 ŌŌÅÂ .ĞǵÅìÂöä ȸƞ Бşɉä Ōƞ 20 øöä
ȳŸȚöä Ž ǿäÂŌϘèŸö ĞŌŸȣţä ĞŸǱɀΣä ȭÅϘƙş ÛǯÂɛ ÛR ȳɀƎèÅƙɀĜöä ÆÂåɀÂ ȸƞ ȟ 1ş TS (ȯ/ȟ190~) ŌÂǿɀÅŸÊöä Ȑƥ

TS ÀÎÄöä òÀŧȞǭèÀæ ÛVS (ò/òɀŋ 0.1) ÿɀÀẩɀÔöä ğÀÄŸèɀǬ òɀŸꞪŋ ÀÄȞÄş ŏÀŋ Ōŋ 100 ȣÀȒÄ .ĘəÀęẩ 5 gÆŋ

ğÀꞪƐꞪÔǨ ĞÄÜ ʔÀϴş Ğòɀ ꞪÀţä gẩÀţä ɹşẩ ĞƐŸŧȞöä ẩÀȞǨ .ÀȒǹÜ – àøàÜ ɹɀö ʔŸȝ òɀÔƩä ʔøǬǵ ÛÀȞÎŧȭ

.$C_{16}H_{18}ClN_3S$ ŊŸŋ 10.66 ŏżÀÒÄ VS (ò/òɀŋ 0.0167) ÿɀƐèÀǩɀĞöä ğÀŋşÀȭ ɄəÀǭ òɀŸƮ ȸŋ Ōŋ 1 Ōȭ .ĞÄøşÀȑ

Ĭ øǳŝΘǁ üƑǄƴƚƨǘǁ ɱɣǷǄǁ !ǸĭǳĭǳǸĭǨ üĭǩĭǄǁ ɷĭƥǸǂǀ üǖǓ ĬȝƑƮä ƒǂƱƗǄ

Additional requirement for Methylthioninium chloride for parenteral use

.(56 ĞꞪÀÔöä Û4 ÆŸÕä ÀƮǭä) "*parenteral preparation* ĞƐÀŌƩä ğäÀȒꞪǬÊţä" øæ ĞòÀʅä gẩşÀɀȡö ÆƐǲɀǬÊÄ

øÀĞǬǹɍä" ɹäɀÄȝ ǨƠ ȣɀòɀŋ ɀȽ Àŧȭ øÀĞǬǹɍä ʔÀƶ :**Bacterial endotoxins** ĞƐŋɀǭÀƨä ĞƐŸǹäÆöä ğÀɸÀÄØöä

Û(ĞÄÀƐŸʊɋä ĞȞĞÛöä Ž 30 ĞꞪÀÔöä Û5 ÆŸÕä) "Test for bacterial endotoxins ĞƐŋɀǭÀƨä ĞƐŸǹäÆöä ğÀɸÀÄØöä ŌǲɈ

.ŊŸŋ 1 Ōȭ Ž RS ɄŸǹäÆöä ɹÀÄØöä ȸŋ ĞƐöşẩ gÆǵş 2.5 ȸŋ ÀǯȭÜ ɃɀǬƠɍ

øøøøø

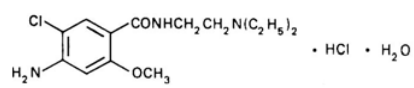
METOCLOPRAMIDI HYDROCHLORIDUM

Metoclopramide hydrochloride ɷĭǄǫƥĜǸǂǀǸǂƗĭǄǁ ɷĭƥǸǂǀǸƥɷĭǉ

$C_{14}H_{22}ClN_3O_2,HCl,H_2O$:**Molecular formula** ĞƐÀÄÂƨä ĞȣƐÔöä

354.3 :**R elative molecular mass** ĞƐĞÊÄöä ĞƐÀÄÂƨä ĞŸǬÒöä

:**Graphic formula** ĞƐɸÀƐĞţä ĞȣƐÔöä



:**Chemical name** ɄəÀƐŧƐÒöä ɭèɍä

4-Amino-5-chloro-*N*-[2-(diethylamino)ethyl]-*o*-anisamide monohydrochloride monohydrate; 4-amino-5-chloro-*N*-[2-(diethylamino)-ethyl]-2-methoxybenzamide monohydrochloride monohydrate; CAS Reg. No. 54143-57-6 (monohydrate).

.ÀĞÄÀŌǨ ĞꞪəäÀöä ĈÆȝ şÜ ĞꞪəäÀöä ĈÆȝ ÛÀĞÄÀŌǨ ȒƐæÜ şÜ ȒƐæÜ ɹɀŸæ ɃøɀŸæ àɀꞪÊŋ :**Description** Ɀòɀöä

Ž ɹÀæşØöä ŌƐŸę ÛTS (ò/ȟ750~) òɀɸÀǯÄɋä Ž ɹÀæşØöä Àǵ ÛöÀţä Ž ÀÆǲ ǡäşæ :**Solubility** ĞƐɸÀæşØöä

.R Ǩǭɉä Ž ÀƐŸŧȝ ǡäşæ Ƙȡ ÛR ÿøɀɀşøɀŸÒöä

.ŏɄŌŸö ẩÀȒŋ ŏäşẩ :**Category** ĞÀÄöä

.ŏɀȒöä ȸŋ ĞƐŧƮ ÛÀÆǲ ĞŌŸȣŋ ĞÄşÀǵ Ž ÆŋäÀæɀŸȭɀǬƐţä ÆÄøɀŸȭşøÆƐȽ ŞÀǵ Æƶ :**Storage** ȸÄÂÅǭöä

ғȿ %98.0 ȸʒ ǑǑʌғ ǻɳ ʔŸʒ ǼŦɳǟǞǣʐŸǑʐǬŧʈǟ ǼʌǿʐŸǑȿǿǼŦŁ Ƀʐǫʒ :**General requirement** ÿǺȞǒǟ ǼŸǕǪʈǟ

.ǤǝǺɳŸǒǟ ǥǻǻʈǟ Ɓǘ ʈʐǅǞǒǺǟ ǤǣʐÊȚ Ǘ$C_{14}H_{22}ClN_3O_2,HCl$ ȸɳ %101.0 ȸʒ ǼʌǞʌ

:**Identity tests** ƕǏǸǈǇǁ Ɩ ǁƥƑǤǞǈǁ

.Dȿ Cȿ B ǧǿǺǫǹғǟ ȿǘ Dȿ A ȸʌǿǺǫǹғǟ ȨǤǕǩ ȸǑʐ •

ǨƠ ǦȞǐɉǟ ǦǑǕǺɳ Ž ɄǝʐȒǒǟ ƵŦǕǒǟ ǡǺǣ" ɉǟʐǺʒ ǨƠ ȣʐǒʐɳ ʐŁ ǻʈǑ ǑȞǺǒǟ ȨǤǕʌ :A

ǦȞǐɉǟ Ž ǐǺǑǫɳғǟ ƵŦǖ ȨǣǺǕǪʌ .(43 ǦȞǺǑǒǟ Ǘ1 ǼŸǑǟ) "Spectrophotometry in the infrared regionǿǟǞʈƩǟ

refernce spectrum ɄȞǅǞʈǟ ƵŦǕǒǟ ʒɳ ȿǘ RS ǼŦɳǟǞǣʐŸǑʐǬŧʈǟ ǼʌǿʐŸǑȿǿǼŦŁ ȸɳ ɉǨǺǒǟ ƵŦǕǒǟ ʒɳ ǒǟǞʈƩǟ ǨƠ

.ǼŦɳǟǞǣʐŸǑʐǬŧʈǟ ǼʌǿʐŸǑȿǿǼŦȚ

ǻɳǼʌʒ ǗVS (ǒ/ǒʐɳ 0.01) ǑʌǿʐŸǑȿǿǼŦȚǟ ȐƥŽ Ǒɳ/ÿǟǞȡȿǞǑɳ 20 ǞŦǑǞǪǣ ǒʐŸǂ ǐǺǑǫɳғǟ ƵŦǖ ɃǼǤʌ :B

ɳŸǤʌ ǗǞǪɳʐǫǺǫ 309ȿ ǞǪɳʐǫǺǫ 273 ǦǟǞȩ ƙŦʈȚʒǘ ƙǑǺǑǪɳǟ ǗǞǪɳʐǫǺǫ 350ȿ ǞǪɳʐǫǺǫ 230 ƙǣ ǯǟʐɳɉǟ ǒǟʐǖǘ Ž ǼŁǺǐʌ

.Ɓǟʐǫǒǟ ʔŸʒ Ǘ0.69ȿ 0.79 ǦǟǞȩ ƙǪǅʐʈǟ ƙǨǞŁ ǒʐǖ Ž ɭȅ 1 ǦǫǺǺǯǣ ǦǑǤǖ ǐǺǫ

ƁǺǑǨǞǣ ɉʐǒ ǰǪʌ ǗTS5 ǼŦŁǼǒǟǞøǞǣ ʐǼɳǘ ǑǯŦɳ ɄǝǺǫ-4 ǒʐŸȚ ȸɳ Ǒɳ 5 ȣǺȒʌȿ ǒǺɳ Ǒɳ 5 Ž ȟ 0.05 ǡǟǾʌ :C

.ǞǞǒǘ -

General ǦɳǺȞǒǟ ȣǟǞȞǫȅғǟ ǧǟǿǺǫǹǟ" ɉǟʐǺʒ ǨƠ ȣʐǒʐʈǟ A ǑʒǺǞǪǒǟ Ǒɳ/ɳŸɳ 20 ǞŦǑǞǪǣ ǒʐŸǂǟ ɄǕȞʌ :D

.(121 ǦȞǺǑǒǟ Ǘ1 ǼŸǑǟ) ǧǟǼʌǿʐŸǑŸǑ ǞɃʈɳ ǑʒǺǞǪǑ "identification tests

ƁǺʅǟ ǒǺʈǟ ȸɳ Ǒɳ 10 Ž ȟ1.0 ǞŦǑǞǪǣ ǒʐŸǂǟ ɉʐǑʌ :**Clarity and colour of solution** ǒʐŸǂǟ ɉʐǒȿ ǒǺǞǒ

ǦǫǿǺǑʈǟ Ǽʌʒ Yw3 ɃǿǺǼȞʈǟ ɉʐŸǒǟ ǒʐŸȚ ɉʐǒ ȸɳ ǞǯǑǘ ɉʐŸǒǟ ǥǼɉ ɉʐǑǨ ғȿ ǞŦʐǺǒ R ɉʐǣǞǑǒǟ ǼŦÊǑǞ ɄǝǺǫ ȸɳ

.(53 ǦȞǺǑǒǟ Ǘ1 ǼŸǑǟ) "colour of liquids ǑǟʐÊǒǟ ɉʐǒ" ɉǟʐǺʒ ǨƠ ȣʐǒʐɳ ʐŁ ǻɳ ǼÊШ

.ȟ/ɳŸɳ 1.0 ȸʒ ǼʌǞʌ ғ :**Sulfated ash** ǨǺŸÊʈǟ ǻǻɳǞǒǟ

Determination of water by ǞǐŦʐ ǒǿǺǑ ǦǑʌǞǕǣ ǒǺʈǟ ƙŦȞǩ" ɉǟʐǺʒ ǨƠ ȣʐǒʐɳ ʐŁ ǻʈǑ ȸŦȞʌ :**Water** ǒǺʈǟ

ʔʐǪȚ ǑǑʌ ғ Ǘǥǻǻʈǟ ȸɳ ȟ 0.5 ǦǟǞȩ ÿǟǼǺǪȅǺǣ Ǘ(145 ǦȞǺǑǒǟ Ǘ1 ǼŸǑǟ) A ǦǑʌǞǕǒǟ Ǘ"the Karl Fischer method

.ȟ/ɳŸɳ 55 ȸʒ ǡȿǾǩ ғ ȟ/ɳŸɳ 45 ȸʒ ǒǺʈǟ

6.5- ǗR ɉʐǣǞǑǒǟ ǼŦÊǑǞ ɄǝǺǫ ȸɳ ƁǺʅǟ ǒǺʈǟ Ž Ǒɳ/ȟ0.10 ǞŦǑǞǪǣ ǒʐŸȚ ǒǺŁǺǣ ʒŸǤʌ :**pH Value** ǒǺŁǺǤǒǟ ǦʈŦȩ

.4.5

ǦǑŦȩǞǒǟ ǦǑǕǕǒǟ ǡǟǞǐǪȅǟ" ɉǟʐǺʒ ǨƠ ȣʐǒʐɳ ʐŁ ǻʈǑ ǿǺǫǹғǟ ȨǤǕʌ :**Related substances** ǦǑǺǐʈǟ ǻǟʐʈǟ

95 ... R4 ... (84 ... 1 ...) "Thin-layer chromatography 5 ... TS (260~) ... 5 R ... -1 ...
:(B) ... 1 ... 50 ... :(A) ... R ...
... 1 ... 0.50 ...
A ... (254) ...
.B ...

... 10 ... R ... 80 ... 0.3 ... :**Assay** ...
... VS (0.1) ... TS ...
1 ...) A ... "Non-aqueous titration ...
.$C_{14}H_{22}ClN_3O_2$,HCl ... 33.63 ... VS (0.1) ... 1 ... .(142 ...

Additional Requirements for Metoclopramide hydrochloride for parenteral use

.(56 ... 4 ...) "*Parenteral Preparations* ...
..." ... :**Bacterial endotoxine** ...
(... 30 ... 5 ...) "Test for bacferial endotoxins ...
... RS ... 2.5 ... 1 ...

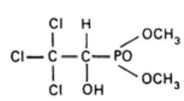
METRIFONATUM

Metrifonate

.$C_4H_8C_{l3}O_4P$:**Molecular formula**

257.4 :**Relative molecular mass**

:**Graphic formula**



Chemical name: [illegible]

Dimethyl (2,2,2-trichloro-1-hydroxyethyl)phosphonate; CAS Reg. No. 52-68-6.

Description: [illegible].

Solubility: [illegible] (~750) TS [illegible] R.

Category: [illegible] Antischistosomal.

Storage: [illegible].

Additional information: [illegible]

REQUIREMENTS [illegible]

General requirement: [illegible] 95.0% [illegible] 101.0% [illegible] $C_4H_8Cl_3O_4P$ [illegible].

Identity tests: [illegible]

A: [illegible] 0.1 [illegible] 0.2 [illegible] R [illegible] 3 [illegible] R [illegible] 7 [illegible] 3 [illegible] (~1000) TS. [illegible] 2 [illegible] B [illegible] 5 [illegible] 2 [illegible] (95) TS [illegible].

B: [illegible] 2 [illegible] A [illegible] 1 [illegible] (0.1) VS [illegible] 3 [illegible] (~100) TS.

Congealing temperature: [illegible] 6.2 [illegible] 85 °C [illegible] 2 [illegible] R [illegible] 80 °C [illegible] "Determination of congealing point" (27 [illegible]) [illegible] 73 °C.

Aceton–insoluble matter: [illegible] 1.0 [illegible] 20 [illegible] R [illegible] 15 [illegible] 10 [illegible] 105 °C [illegible] 1 [illegible]

.ȟ/ŋŸŋ 5.0 ȡʒ ǦǟşæŸöä ǥǻÌţä ʔʐǪȚ

.ȟ/ŋŸŋ 3.0 ȡʒ ǼȽÂȽ ғ :**Sulfated ash** ǨÀŸÊţä ǻÌŋÀ̀öä

Determination of water by ÀÎȄ ȯǿÌõ ǦÕȽÀÛǣ öÌţä ƙǄȞǩ" ȷäʐȺʒ ǨƠ ȣʐȯ̀ʐŋ ʐȽ Ìȶõ ȡǄǨȽ :**Water** öÌţä ʔʐǪȚ ǼȽÂȽ ғ ÜǥǻÌţä ȡŋ ȟ 1 ÿäǼǺǪèÀǣ Û(145 ǦȞÀÔöä Û1ǼŸǑä) A ǦÕȽÀÛöä ǼÊƜ Û"the Karl Fischer method .ȟ/ŋŸŋ 7.5 ȡʒ öÌţä

.3.5-2.0 Û Ōŋ/ŋŸŋ5.0 ÂȄõÀ̀Ǫǣ ȯʐŸǂä öÌȽÀǣ ŋŸǤȽ :**pH Value** öÌȽÀǤöä ǤȶȄę

ȯʐŸȚ ȡŋ Ōŋ 10 ȣÌȒȽ .Rȯʐ̀φÌǯȄţä ȡŋ Ōŋ 90 Ž ÛǤȄùʐǤȒŋ Ǥφşàʐŋ Ûȟ 1.0 ǦǟäÀę ā äǾȽ :**Assay** ǦÊȽÀŌţä 10 ǥǼŋ ȢDzŸǭ ÿÀþ Ž ǻƎȽ ǾəǼȺʒ .Ǧʒ̀Ìè 1 ǥǼŋ °ÿ 0.5±20 ǦDZǿǼǣ ǿäÀŌǪèŸö ȯʐŸǂä ȭÀǪȽş monoethanolamine R 0.1) ǦȒÀöä ǧäÀ̀Ǫφ ȯʐŸȞŋ °ÿ 20 ǥǿäÀǵ ǦDZǿǼǣ ÀȽÌȞȽş ÛTS (ȯ/ȟ1000~) ŌȽÀ̀ǪȽöä Ȑþ ȡŋ Ōŋ 20 ȣÌȒȽ ÛĘəÌęǻ ʔÀ̀Êȶ) ǻşÀ̀ǪȮöäş ƙǨŸǤöä ȡŋ (ŸÀ̀ǼȚǭ ʔÀ̀Êȶ) ǻşÀǪȮöä ÿäǼǺǪèÀǣ ǼƮƨä âÌȄŌŋ ǦȽƮȽöä ǦÛŌφ ȡǄǨǩş ÛVS (ȯ/ȯʐŋ VS (ȯ/ȯʐŋ 0.1) ǦȒÀöä ǧäÀ̀Ǫφ ȯʐŸȚ ȡŋ Ōŋ 1 Ōõ .calomel reference electrode ȢǨDZÀ̀ŋ ŌȄŋʐöÀõ (ȢǿǣÀ̀ǼȚǭ .$C_4H_8Cl_3O_4P$ ȡŋ ŋŸŋ 25.74 öżÌȮȽ

ǾǾǾǾǾ

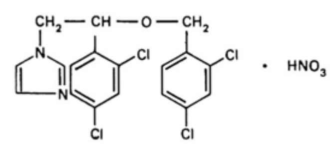
MICONAZOL NITRAS

Miconazole Nitrate üǋȐǅǆǋǀȉǅǁȨ ǀƐþǂǆ

$C_{18}H_{14}C1_4N_2O,HNO_3$:**Molecular formula** ǦȄÌȽÂƨä ǦȣȄÔöä

479.2 :**Relative molecular mass** ǦȄǤÊȽöä ǦȄÌȽÂƨä ǦŸǪȮöä

:**Graphic formula** ǦȄφÌȄǤţä ǦȣȄÔöä



:**Chemical name** ȢəÌȄȶȄȮöä ȴèғä

1-[2,4-Dichloro-β-[(2,4-dichlorobenzyl)oxy]-phenethyl]imidazole mononitrate; 1-[2-(2,4-dichlorophenyl)-2-[(2,4-dichlorophenyl)methoxy]-ethyl]-1*H*-imidazole mononitrate; CAS Reg. No. 22832-87-7.

.ǄǤȽÀŌǨ ǦȞəäÀöä ƇǼʒ şÛ ǦȞəäÀöä ƇǼʒ ÛǄǤȽÀŌǨ ȐȄǣÛ şÛ ȷʐŸöä ȐȄǣÛ ÜȼǿʐŸǣ àʐȞÊŋ :**Description** Ȥȯʐöä

ÜTS(ȯ/ȟ750~) ȯζφǺǯΛɋä ȸɳ ǆȱÂDZ 140 Ž āäşæ ÜR ƘǭɟǟȘ ŏǺţä Ž ǆÆDZ ɹǺæşǾöä ǴǂHʋì :**Solubility** ǦǂφǺæşǾöä
.R ÿǿζζşǿζŸȮöä Ž ɹǺæşǾöä ǴǂHʋì

.ğǺΛÀÛAöä åǺȒɳ ŏäşå :**Category** ǦǺAöä

.ŏζȒöä ȸɳ ʡŧHʋǩ ɹǕş ǕǆÆDZ ǦǑŸ8ɳ ǦΛşǺǵ Ž ȘȦƠ ɹǕ Ƶ ȯşàǺφζȮǂţä ğäÀφ :**Storage** ȸΛÂǺǬöä

.ȰȯAǬöä Ʒɳ °ÿ182 ǦDZǿÆöä Ž ȯşàǺφζȮǂţä ğäÀφ ÀȚȎAǩ :**Additional information**ȂǦǂζǺȓǕ ğǺɳζŸĦɳ

REQUIREMENTS ƘǦǂǷȰkdž!ƒ

ȸƷ ÆΛÂΛ ɼş %98.5 ȸƷ ǬǑΛ ɼ Ǻɳ ʡŸƷ ȯşàǺφζȮǂţä ğäÀφ ɃζǬƠ :**General requirement** ÿǺĦöä ÆŸÛǬţä
.ǦǺAȮöä ğåǺţä ƃǕ ţζDZÀöǺæ ǦæζȆȚ Û$C_{18}H_{14}C1_{4}N_{2}O,HNO_{3}$ ȸɳ %101.5

:**Identity testes** ɧĭǊǇǁ l ɛþƑǴɪɛ

- .Cş B ɹäǿǺǬȵɼä şǕ ȻÆǵş A ǿǺǬȵä ĘǥÛΛ ɹǕ ǺɳǕ

öäÀŧΣä ǨƠ Ǻɳ ǦǑÛAɳ Ž ɄaζȒöä ȤǂÛöä âǺǂę" ɹäζΛƷ ǨƠ 8ζȍζɳ ζȽ Ǻŧȭ ǿǺǬȵɼä ɃÀƵ :A
öäÀŧΣä ǨƠ ǦĦì ɟä ȋ ǺȎǬɳä ȤǂȕĘæǺÛǬΛ .(40 ǦĦʋǺȎöä Û1 ÆŸȮä) "Spectrophotometry in the infrared region
.ȯşàǺφζȮǂţä ğäÀǬǺö ɄĦDZÀţä ȤǂÛöä Ʒɳ şǕ RS ȯşàǺφζȮǂţä ğäÀφ ȸƷ ǰǨΛAöä ȤǂÛöä Ʒɳ

ȸɳ Æǵäş ȴDzǵş R ȯζφǺǯǂţä ȸɳ ÿǺDzǵǕ 9 ȸɳ ǰΛÂɳ Ž Ǭɳ/ɳŸɳ 0.40 ÂǂȭÀǬæ ȯζŸƚ ȋ ǺȎǬɳɼä Ȥǂù ɳŸǤΛ :B
ÆΛƷ ǂŧȚƷǕ ǂÆǵ ÛÀǬɳζφǺφ 350ş 230 ƙæ ǦDZζɳ ȯäζùǕ Ž ÆȽǺȊΛ ǺɳÆΛƷ ÛVS (ȯ/ȯζɳ 0.1) ȭΛǿζŸȭşǿÆǂTä Ȓþ
ȯäζùǕ Ž ȴè1 ǺȚǬφǺǺǭ ǦǑǤù Ʒƺ ǂǤΛÀǑǩ ȋ ǺŧǬöä ɳŸǤΛş .ǂǤΛÀǑǩ ÀǬɳζφǺφ 280ş ÀǬɳζφǺφ 272ş ÀǬɳζφǺφ 264 ǦDZζţä ȯäζùǕ
.ƃäζǬöä ʡŸƷ 0.58ş 0.48ş 0.40 ȭŸǩ ǦDZζţä

ÿζǂèǺǩζǤöä ÆΛǿζŸȭ ȸɳ Ǭɳ 0.4 ȣǺȒΛ ÛǂåǿǺæ ĘŸĦţä ȘǺƷ .ÆǂŸƨä ÿǺþ Ž åǂHǩş ŏǺţä ȸɳ Ǭɳ 5 Ʒɳ Ǭɳ10 ǯǺǂ :C
Ȓþ ȸɳ Ǭɳ 5 ǯǺöä Ʒɳ ÛğÀÛę ÀǬǕ ğÀÛęş ÜTS ȭΛǿζǺŸè Ȓþ/ƙɳŸǂÆǂζ ɄaǺǬ ȸɳ Ǭɳ 0.1ş TS (ȯ/ɳɳ100)
.ÆΛÆì ȧǿäǕ ɹζȯ ǰǬΛΛ ÜTS (ȯ/ȟ 1760~) ȭΛǿζǺŸȆöä

.ȟ/ɳŸɳ 2 ȸɳ ÀǯȭǕ Ȉǂö :**Sulfated ash** ǨǺŸȆţä åǺɳÀöä

ÆΛÂΛ ɼ) ȒǺǺAɳ Ù8ȓ ǨƠ °ÿ100 ǦDZǿå ÆΛƷ ǨæǺǭ ɹàş ʡǿǬǵ ȤǺƵ :**Loss on drying** ȤǂÀDzǬǺæ ÆǑÀöä
.ȟ/ɳŸɳ 5 ȸɳ ÀǯȭǕ ÆǑÀöä ɹζȮΛ ɼ .(ǂǤΛÀǑǩ ɄǑǤà ȴɳ 5 şǕ ȯǺȮèǺæ ζŸǂȭ 0.6 ȸƷ

ǦǑǂęÀöä ǦǑǤÛöä āäÀȊǬèä" ɹäζΛƷ ǨƠ 8ζȍζɳ ζȽ Ǻŧȭ ǿǺǬȵɼä ɃÀƵ :**Related substances** ǦǒǺȊţä åäζţä
Ȥöǘɳ ǰΛÂɳş ǦŸǂ8ɳ ğåǺŧȭ R1 ǂȮǂŸǂȆöä ǦɳŸȽ ÿäÆǺǬèǺæ (84 ǦĦʋǺȎöä Û1 ÆŸȮä) "Thin-layer chromatography

[illegible] R [illegible] 10 R [illegible] 30 R [illegible] 60 [illegible] 50 [illegible] TS (260~) [illegible] 25 (B) [illegible] 10 (A) [illegible] R [illegible] R [illegible] (A) [illegible] TS [illegible] B [illegible].

[illegible] R1 [illegible] 50 [illegible] 0.35 [illegible] :**Assay** [illegible] Potentionetrically [illegible] VS (0.1) [illegible] (142 [illegible] 1 [illegible]) A [illegible] "Non-aqueous titration [illegible]" [illegible] $C_{18}H_{14}Cl_4N_2O,HNO_3$ [illegible] 47.92 [illegible] VS (0.1) [illegible].

NALOXONI HYDROCHLORIDUM

Naloxone hydrochloride [illegible]

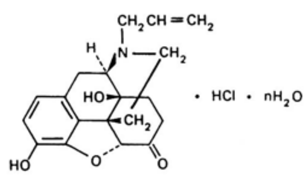
Naloxone hdrochloride, anhydrous [illegible]

Naloxone hdrochloride, dihydrate [illegible]

[illegible] **:Molecular formula** $C_{19}H_{21}NO_4,HCl$ ([illegible]) $C_{19}H_{21}NO_4,HCl,2H_2O$ ([illegible]).

[illegible] **:Relative molecular mass** 363.8 ([illegible]) 399.9 ([illegible]).

[illegible] **:Graphic formula**



n = 0 (anhydrous)
n = 2 (dihydrate)

[illegible] **Chemical name:**

(–)-17-Allyl-4,5*a*-epoxy-3,14-dihydroxymorphinan-6-one hydrochloride; 4,5*a*-epoxy-3,14-dihydroxy-17-(2-propenyl)morphinan-6-one hydrochloride; (–)-12-allyl-7,7a,8,9-tetrahydro-3,7a-dihydroxy-4a*H*-8,9c-imino-ethanophenanthro[4,5-*bcd*]furan-5(6*H*)-one hydrochloride; CAS Reg. No. 357-08-4 (anhydrous).

(–)-17-Allyl-4,5*a*-epoxy-3,14-dihydroxymorphinan-6-one hydrochloride dihydrate; 4,5*a*-epoxy-3,14-dihydroxy-17-(2-propenyl)morphinan-6-one hydrochloride dihydrate; (–)-12-allyl-7,7a,8,9-tetrahydro-3,7a-dihydroxy-4a*H*-8,9c-imino-ethanophenanthro[4,5-*bcd*]furan-5(6*H*)-one hydrochloride dihydrate; CAS Reg. No. 51481-60-8 (dihydrate).

[illegible] **Description:** [illegible]

[illegible] **Solubility:** [illegible] (750~ [illegible]) [illegible] R [illegible]

[illegible] **Category:** [illegible]

[illegible] **Storage:** [illegible]

[illegible] **Labelling:** [illegible]

Additional information [illegible] 177 [illegible]

REQUIREMENTS [illegible]

[illegible] **General requirement:** [illegible] %98.0 [illegible] %102.0 [illegible] $C_{19}H_{21}NO_4$,HC1 [illegible]

[illegible] **Identity testes:**

- [illegible] A [illegible] B [illegible] C.

A: [illegible] "Spectrophotometry in the infrared region" [illegible] (43 [illegible] 1 [illegible]) [illegible] RS [illegible]

B: [illegible] 0.05 [illegible] 5 [illegible] (0.1 [illegible]) VS [illegible] 0.3 [illegible] (25 [illegible]) TS [illegible]

General ǦŋẢĤǒä ȣäÀĤϘèɼä ǧäøẢǤϘǹä" ɈäζẢȝ ǨƠ ȣζòζƫä A ǑȝẢẢϘǒä Ǒŋ/ŊŸŋ 0.05 ÂĿÕÀϘǽ òζŸƮ ƱÛĤǺ :C
.(121 ǦĦẢÔǒä Û1 ǼŸǑä) ǧäǼǺøζŸȮŸǒ ÂĿƭƭÕ "identification tests

БǗ ƫζǄÀǒẢǽ ÆÊƷș Ǒŋ/ŊŸŋ 25 ÂĿÕÀϘǽ òζŸƮ ÿǼẢϘÊǺ :**Specific optical rotation** ƱȝζẢǒä ɃÀÔǤǒä ÀǺşǼϘǒä
$.[a]_D^{20°C}$ = -170 to-181° ǦẢÀǑä ǥẢƫä

ǼǺøζŸÕşøǼĿȽ ǼǑζ ɈζȮǺ ɼ .°ÿ105 ǦǄøǼǽ ǨǽẢϘ ɈÀș ʔøϘǵ ζÀƵ :**Loss on drying** ζĿǍǄϘǒẢǽ ǼǑÀǒä
110 ȸŋ ÀǮÕǗ ǧäøǼĿȽä ƱǝẢÀϘ ɈζÊÕζǒÀǒä ǼǺøζŸÕşøǼĿȽ ǼǑζ ɈζȮǺ ɼș Ûȟ/ŊŸŋ 5.0 ȸŋ ÀǮÕǗ ƱǝẢŋŸǒä ɈζÊÕζǒÀǒä
.ȟ/ŊŸŋ

ǦǑĿęÀǒä ǦǑǤÛǒä ǡäÀÎϘèä" ɈäζẢȝ ǨƠ ȣζòζŋ ζȽ Ảƭ̃Õ øẢǤϘǹɼä ɃÀƵ :**Related substances** ǦǒẢÎƫä ǻäζƫä
ǑĿǒẢɫä ÀȒƠș ÛR1 ǦŸĬ8ŋ ǥẢƭÕ ẢȮĿŸĿÊǒä ǦŋɎȽ ÿäǼẢϘèẢǽ Û(84 ǦĦẢÔǒä Û1 ǼŸǑä) "Thin-layer chromatography
ǦǑǤÛǒä ǳÀÛĸ ÛTS (ò/ȟ 17~) ẢĿϙζŋɉä ȸŋ Ǒŋ 60 Ʒŋ R òζϙẢǩζǽ -1 ȸŋ Ǒŋ 100 ŗÀĿ :ÕÀĦϘŋ øζÛÕ ǦĿǒẢϘǒä
ɎÔẢẢŋ ĘǭÛǺ .ǒäζȽ øẢĿǩ Ž ǦĦĿẢÔǒä ζẢƟ .R òζϙẢǮĿƫä ȸŋ ÿζǄǵ 5 Ʒŋ ẢĿŸĤǒä ǦǑǤÛǒä ȸŋ ẢƭǄǵ 95 ǯÂƺș ÛʔŸẢÊǒä
2 Ž ɈζÊȮǒẢẢǒä ǼǺøζŸÕşøǼĿȽ ȸŋ ŊŸŋ 40 ǡäǾǺ (A) òζŸɫä ǑǄɉ :ƙĿǒẢϘǒä ƙòζŸɫä ȸŋ ÀϘǒşÀȮĿŋ 5 ǦĦĿẢÔǒä ʔŸȝ
òζϙẢǮĿƫẢǽ Ǒŋ 100 ʔøϘǵ A òζŸɫä ȸŋ Ǒŋ 0.5 ζẢƩ (B) òζŸɫä ǑǄɉ ÛR òζϙẢǮĿƫẢǽ Ǒŋ 5 БǗ ζẢƩș ǒẢƫä ȸŋ Ǒŋ
ǽÀǩ ÛǒäζȽä Ž ζǄϘǒ ÕÀϘǩ ǡäÀÎϘèɼä ǥÀǄǵ ȸŋ ǦĦĿẢÔǒä ƫÂϙ ǼĤǽ .ǒζȒǒä ȸŋ ẢĿƭƮ ǡäÀÎϘèɼä ÙÛƠ ÀȽƮĿ ÛR
.øẢȽẢǒä ǒζȓ Ž ǡäÀÎϘèɼä ÙÛƠ ÒĦẢẢș ÛTS ÿζĿèẢǩζǤǒä ǼĿϙẢĿè ɃƙζȽ /ǑǺǼǺǼƩä ǼǺøζŸȮǽ
.(%0.5) B òζŸɫä ȸŋ ǦƟẢǒä ǑŸǩ ȸȝ ǥǼȉ ÀǮÕǗ ÛǤĿÊĿǝÀǒä ǦĤǑǤǒä ǒẢǮϘèẢǽ ÛA òζŸɫä ȸŋ ǰϘẢǩ ǦĤǑǽ ǦǺǗ ɈζȮǩ ɼ
.ĘĿǤÛϘǒä ǦÛǑϙ Ž ʔǑǤǩ ǦĤǑǽ ɃǗ Ǒƭő

ȣẢȒǺ .R òζϙẢǮĿƫä ȸŋ Ǒŋ 50 Ž ÛǤĿùζǤȒŋ ǦϙşàζŋÛȟ 0.3 ǡäǾǺ :**Chlorides content** ǧäǼǺøζŸȮǒä ʔζϘƮ
VS (ò/òζŋ 0.1) ǦȒẢǒä ǧäÀϘǽ ÀǺẢĤǺș ÛTS (ò/ȟ 5) Y ȸǺàζǺɉä ȸŋ Ǒŋ 0.1ș ƱǄζŸǮǒä ǑĿϘèɉä Ȓþ ȸŋ Ǒŋ 5
ɼ ÛøζŸȮǒä ȸŋ Ʒŋ 3.545 ùζẢȮǺ VS (ò/òζŋ 0.1) ǦȒẢǒä ǧäÀϙ ȸŋ ÀϘǒ ƱŸĿŋ Ǽǥäș ǑÕ .ƱŸẢϙÀę ɈζǑ ǰϘǺǺ ʔøϘǵ
.ǦẢÀǑä ǥẢƫä БǗ ƫζǄÀǒẢǽ ǦǽζÊƮ Ûȟ/ŊŸŋ 99.4 ȸȝ ǼǺÂǺ ɼș ȟ/ŊŸŋ 95.4 ȸȝ ǧäǼǺøζŸȮǒä ʔζϘƮ ǬǑǺ

ȸŋ Ǒŋ 10 ȣẢȒǺ ÛR1 ƱǄζŸǮǒä ǑĿϘèɉä Ȓþ ȸŋ Ǒŋ 40 Ž ÛǤĿùζǤȒŋ ǦϙşàζŋÛȟ 0.3 ǡäǾǺ :**Assay** ǦÊǺẢǑƫä
(ò/òζŋ 0.1) ǑǺøζŸÕƘǒä ȒƭШ ÀǺẢĤǺș ÛTS ǑĿϘèɉä Ȓþ/ǑĿǑǝÂǒä ǧẢϘĿèǗ ȸŋ Ǒŋ 10ș R ǑĿϘèɉä ǼǺøǼĿŒǗ
ǦĦẢò Û1 ǼŸǑä) A ǦǑǺÀÛǒä Û"Non-aqueous titration ƱǝẢŋŸǒä Ûèζǒä Ž ǥÀẢĤƫä" ɈäζẢȝ ǨƠ ζòș Ảƭ̃Õ VS
.$C_{19}H_{21}NO_4,HCl$ ȸŋ Ʒŋ 36.38 ùζẢȮǺ VS (ò/òζŋ 0.1) ǑǺøζŸÕƘǽ Ȓþ ȸŋ Ǒŋ 1 ǑÕ .(142

Additional Requirements for Naloxone hydrochloride for parenteral use

.(56 ... 4) "*Parenteral preparations*"

Bacterial endotoxins: ... "Test for Bacterial endotoxins" (... 5 ... 30 ...)

... 500 RS ...

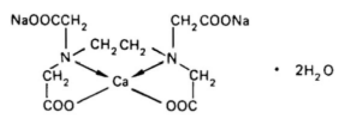
NATRII CALCII EDETAS

Sodium Calcium edetate

Molecular formula: $C_{10}H_{12}CaN_2Na_2O_8,2H_2O$

Relative molecular mass: 410.3

Graphic formula:



Chemical name:

Disodium [(ethylenedinitrilo)tetraacetato]calciate(2–) dihydrate; (*OC*-6-21)-disodium [[*N*,*N*′-1,2-ethanediylbis[*N*-(carboxymethyl)glycinato]](4–)-*N*,*N*′,*O*,*O*′,O^N,$O^{N'}$]calciate(2–) dihydrate; calcium chelate of the disodium salt of ethylenediamine-*N*,*N*,*N*′,*N*′-tetraacetic acid dihydrate; CAS Reg. No. 6766-87-6 (dihydrate).

Description: ...

Solubility: ... (~750 ...) TS ...

... R ... R ...

Category: ...

Storage: ...

Additional information: ...

ÆÂ ɍş %97.0 ȸ ȰŎ ɍ Åŋ ɁŸȝ ȳƺáƺÔöä ȳƺÊöÃõ ğÅǪÆǗ ɃƺǪƠ :**General requirement** ȳÅĽĦöä ÆŸÛǪţä .ǦÅÅŎä ğáÅţä ɃǗ ţƺǱÅöÅǟ ǦǟƺÊƮ Û$C_{10}H_{12}CaN_2Na_2O_8$ ȸŋ %102.0 ȸ

:**Identification tests** ȟŬŇǈǁɛ Ɩɛƥǧǂǆɛ

Ōŋ 6 ȣÅŔÅş ȑÅŀ ÛTS (ȯ/ȟ 100) î ÅòÅöä ğäÅǪ ȸŋ Ōŋ 2.0 ȣÅŔÅ ÛöÅţä ȸŋ Ōŋ 25 Ž ȟ 2.0 āäØÅ :A .(C øÅǪǹɍä ŌǱǗ ȸŋ ȯƺŸǂä ȘÅĦŀ) öäÅÅò ǦǟÅèø ǦÅǗø ȸŎƹ ɍ ǗTS (ȯ/ȟ 80) ȳƺèÅƺǦöä ÆÅáƺÅ ȸŋ ǗTS (ȯ/ȟ75) ȳƺǪƺŋɉä ğÅǪÅèƺǪ ȸŋ Ōŋ 0.15 ȣÅŔÅ TS (ȯ/ȟ25) ȬÅÆÆΣä ÆÅøƺŸõ ȸŋ Ōŋ 0.15 ɃǗ :B .ÅÅòǗ ɃǗ ĘŋÅȣöä Åƥɉä ȷƺŸöä ÅȣǪÅ ǗøÅǪǹɍä ğáÅŋ ȸŋ ȟ 0.05 ǦäÅę ĘŋÅȣöä Åƥɉǟ ȷƺŸţä ȯƺŸǂä äØȽ ɃǗ ȣÅŔÅş ɃƺŸŌöä ŌȝÅÅǪöä ȯƺÔǵ ɁøǪǵ ǥÅÛę ÅǪǗ ǥÅÛę TS (ȯ/ȟ 100~) ÅǪƺŋǗ A øÅǪǹɍǟ ÅŔǂä ȯƺŸǂä ɃǗ ȣÅŔÅ :C ğÅǪÆǗ ȸ ǥÅɯ) öÅŔǟ ǦǟÅèø ȷǪÅ ǗTS (ȯ/ȟ 25) ȳƺǪƺŋɉä ğɍâÅõşǗ ȸŋ Ōŋ 5 ȣÅŔÅ .R öÅŁÅǦöä ÅĦÎŋ ǦęøƺǪ .(ȳƺáƺÔöä ȾəÅÅǪ

General ǦŋÅĦöä ȣäÅĦǪèɍä ğäøÅǪǹä" ȷäƺȝ ǨƠ ȣƺòƺŋ ƺŁ Åȶõ ȳƺáƺÔöä ŌǱǗ ȸŋ øÅǪǹɍä öäÅǱǗ ÆȝÅ :D ǦȶõÅ (ŌĦÎǩ) ÆŋÅŀ ÛB ŌȝÅÅǪöä ȳÆǺǪèä äǽǗ .ǥÅɯ ğȲȝÅǩ ȾÛĦ Û(123 ǦĦÅÔöä Û1 ÆŸŎä) "identification tests .TS (ȯ/ȟ 60~) ȬǪèɉä Ȑƥ Ž ǦöÅȶŽöä āäØǩş ǦŸǪę

øÅǪǹɍä" ȷäƺȝ ǨƠ ȣƺòƺŋ ƺŁ Åȶõ ȟ 1.0 ŌȶĦǪÊÅ øÅǪǹɍä ȯƺŸƮ ƘŔĦǪǪ :**Heavy metals** ǦŸȶŌŽöä ȷáÅĦţä ȜƺǪƮ ȸŋĦ Ǘ(127 ǦĦÅÔöä Û1 ÆŸŎä) ǬÅŽöä öäÅǱǪq "Limit test for heavy metals ǦŸȶŌŽöä ȷáÅĦţä ŌǱɉ ɃÆΣä .ȟ/ȳäÅǭşÅŎŋ 20 ȸŋ ÅŽõǗ ȷƺŎÅ ɍ Ǘ(128 ǦĦÅÔöä Û1 ÆŸŎä) A ǦŎÅÅÛöä ÆÊɯ ǦŸȶŌŽöä ȷáÅĦţä

ÅǪƺŋɉä ȸŋ Ōŋ 4ş R ȳƺèÅƺǦöä ÆÅáƺÅ ȸŋ ȟ 1.0 ȣÅŔÅ ÛöÅţä ȸŋ Ōŋ 50 Ž ȟ 1.0 āäØÅ :**Cyanide** ÆǪÅÊöä ȷƺŎÅ ɍ ǗǥÆǵäş ǦŌȶęá ǥÆŋ øäÅŌǪèŸö ȭÅǪÅş ÛVS (ȯ/ȯƺŋ 0.01) ǦŔÅöä ğäÅǪ ȸŋ Ōŋ 0.10ş TS (ȯ/ȟ 100~) Ōŋ1.0ş TS (ȯ/ȟ 130) ȬÅÅǪÆöä Ȑƥ ȸŋ Ōŋ1 ɁŸȝ ɃƺǪȜ ɃøÅĦŋ ȯƺŸƮ Ž áƺǱƺţä Ȭöǟ ȸŋ ŌęǗ ȷǩÅÅöä ȳƺȶȣöä .VS (ȯ/ȯƺŋ 0.1) ǦŔÅöä ğäÅǪ ȸŋ Ōŋ 0.10ş öÅţä ȸŋ Ōŋ 9ş VS (ȯ/ȯƺŋ 0.0001) ȬÅøƺŸõşøÆǂTä Ȑƥ ȸŋ .ÅŔÅǗ ǥÆǵäş ǦŌȶęá ǥÆŋ ÅŌǪÊǂö ȭÅǪÅ ȷǗ Æƶ ȯƺŸǂä äØȽ

ǦəøäáƑ ȸŋ Ōŋ 10 ȣÅŔÅ ÛöÅţä ȸŋ Ōŋ 20 Ž ȟ 5.0 āäØÅ :**Disodium edetate** ȳƺáƺÔöä ȾəÅÅǪ ğÅǪÆǗ 0.1) ȳƺÂøÅȣţä ÆÅøƺŸõ Ȝŋ ÅÅĦÅş ÛR ÅĦÎŋ ȷÅŋ 11 mordant black ǸèÅŀ áƺèǗ ȸŋ ȟ 0.2ş TS2 ÅǪƺŋɉä .VS (ȯ/ȯƺŋ 0.1) ȳƺÂøÅȣţä ÆÅøƺŸõ ȸŋ Ōŋ 1.5 ȸŋ ÅŽõǗ ÆǂÛǪ ɍ .VS (ȯ/ȯƺŋ

ǨƠ ȣƺòƺŋ ƺŁ Åȶõ ȯƺŸǂä ÅÅĦÅ .öÅţä ȸŋ Ōŋ 40 Ž ǦöÅȶŽöä āäØǩş ȟ 0.5 (ŌĦÎÅ) ÆŋÅ :**Iron** ÆÆΣä

80 [illegible] (129 [illegible] 1 [illegible]) "Limit test for iron [illegible]" [illegible]

Determination of water by [illegible] **Water** [illegible] 0.2 [illegible] (145 [illegible] 1 [illegible]) A [illegible] "the Karl Fischer method [illegible] 130 [illegible]

pH [illegible] 0.2 [illegible] 8.0-6.5 [illegible]

Assay [illegible] 0.5 [illegible] 90 [illegible] 7 [illegible] 5 R [illegible] 70~) [illegible] .TS [illegible] (0.05 [illegible]) VS [illegible] 18.71 [illegible] (0.05 [illegible]) VS [illegible] 1 [illegible] .R [illegible] $C_{10}H_{12}CaN_2Na_2O_8$.

[illegible]

Additional Requirements for Sodium Calcium edetate for parenteral use

[illegible] "*Parenteral preparations* [illegible] (56 [illegible] 4 [illegible]).

Bacterial endotoxins [illegible] "Test for Bacterial endotoxins [illegible] (30 [illegible] 5 [illegible]) [illegible] 0.2 RS [illegible]

NATRII CITRAS

Sodium citrate [illegible]

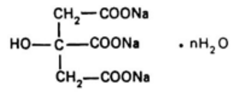
Sodium citrate, anhydrous [illegible]

Sodium citrate, dihydrate [illegible]

Molecular formula [illegible]: $C_6H_5Na_3O_7$ ([illegible]) $C_6H_5Na_3O_7,2H_2O$ ([illegible]).

Relative molecular mass [illegible]: 258.1 ([illegible]) 294.1 ([illegible]).

[illegible] :**Graphic formula**



n = 0 (anhydrous)
n = 2 (dihydrate)

[illegible] :**Chemical name**

Trisodium citrate; trisodium 2-hydroxy-1,2,3-propanetricarboxylate; CAS Reg. No. 68-04-2 (anhydrous).
Trisodium citrate dihydrate; trisodium 2-hydroxy-1,2,3-propanetricarboxylate dihydrate; CAS Reg. No. 6132-04-3 (dihydrate).

[illegible] :**Description** [illegible].

[illegible] :**Solubility** [illegible] (750~ [illegible] TS R [illegible].

[illegible] :**Category** [illegible].

[illegible] :**Storage** [illegible].

[illegible] :**Labelling** [illegible].

[illegible] :**Additional information** [illegible].

REQUIREMENTS [illegible]

[illegible] :**General requirement** [illegible] %99.0 [illegible] %101.0 [illegible] $C_6H_5Na_3O_7$ [illegible].

[illegible] :**Identification tests**

A: [illegible] General "identification tests" [illegible] (123 [illegible] 1 [illegible]) [illegible] B [illegible] 20 [illegible].

B: [illegible] 20 [illegible] B [illegible] General "identification tests" [illegible] (121 [illegible] 1 [illegible]).

øÅǬǹɍǟ" ɉǟ̤ǻȝ ǨƠ ȣ̤ǒ̤ǹ ̤Ƚ Åȶõ ȟ 1.0 ŌȶȞǬÊ ǿÅǬǹɍǟ ȯ̤ǙȚ ƘȒǶǬǿ :**Heavy metals** ǦǛĒŌǰǿǟ ɉấÅȞţǟ

Ɂ̤ǬȚ ȸǂǶȞ Ǘ(127 ǦǶÅÔǿǟ Û1 ǼǛǑǟ) ȯȘɉǟ ǿǟÀDZɋǟ "Limit test for heavy metals ǦǛĒŌǰǿǟ ɉấÅȞţǟ ŌDZɉ ɃǼΣǟ

.ȟ/ȳǟÀȡȘÀȮȠ 10 ȸȠ ÀǰõǗ ɉ̤ȮÅ ɍ Ǘ(128 ǦǶÅÔǿǟ Û1 ǼǛǑǟ) A ǦŌÅÀÛǿǟ ÆÊШ ǦǛĒŌǰǿǟ ɉấÅȞţǟ

(ȯ/ȟ 420~) ǼÅǿ̤ǛõȘǿǼĒȚǟ Ȑ ƥ ȸȠ ŌȠ 3 ȣÅȒÅ ÛǿÅţǟ ȸȠ ŌȠ 4 Ž ȟ 0.5 ǟǟǾÅ :**Oxalates** ǧɍÅÊõȘɉǟ

ŌǝÅÊǿǟ ȹÆÔÅ ÛǦŌĒȩấ 2 ǥǼȠ ǿǟÀŌǬèƳǿ õÀǬÅ .ǥǼǵǟȘ ǦŌĒȩấ ǥǼȠ ȗǝÅȠ ȳÅƥ Ž ȸÁÊÅȘ ÛR ÆǬɉǟ ŌȹÂǿǟ ȸȠ ȟ 1Ș TS

ấǶǶÅ .ɉÅĒǛȣǿǟ ɁøǬǵ ȸÁÊÅȘ ÛTS (ȯ/ȟ 10) ȸÅǟǟǿǼĒȽ ŌĒǼÀǿǟ ǼÅǿ̤ǛõȘǿǼĒȽ ȸȠ ŌȠ 0.25 Ƀ̤ȝ ǿÅǬǹǟ ǟ̤ǦǬǗ Ž

ŌȠ 0.25 øǟ ȝǦǬÅ Û(ȯ/ȟ 420~) ŌÅǿ̤ǛõȘǿǼĒȚǟ Ȑ ƥ ȸȠ ȯấÅȞȠ ȴDZǵ ȣÅȒÅȘ ÛǦDZȹǼȠ ǦǬǟ̤ÛèǗ БǗ ŌŌÅÅ ÛǶȞÅÀè

ɉ̤ȮÅ ɍ ǰǬÅÅ ȗøǬǟ̤DZǿǗ ɉ̤ǿ ɃǗ ǗǦŌĒȩấ 30 ǥǼȠ ǿǟÀŌǬèƳǿ õÀǬÅȘ ǥÀł .TS (ȯ/ȟ 50) ȳ̤ĒèÅǨ̤Ǧǿǟ ǼĒǬÅĒè ɃƘ̤ ȸȠ

.TS (ȯ/ȟ0.05) ŌĒǿÅÊõȘɉǟ Ȑ ƥ ȸȠ ŌȠ 4 ɃȘÅΣǟȘ ǦǛǬÅư ǦŌÅÀÛǟ žÅȞţǟ ȯ̤Ǜɉǟ Ōǿǽ ɉ̤ǿ ȸȠ ǥǼì ÀǰõǗ

ȗǝÅÅǬ ȸȠ БÅʅǟ ǿÅţǟ ȸȠ ŌȠ 10 Ž ȟ1 ȯ̤ǛȚ ɉ̤ȮÅ :**Clarity and colour of solution** ȯ̤Ǜɉǟ ɉ̤ǿȘ ǿÅÅÔǿǟ

.ɉ̤Ǜǿǟ ǇǼȝȘ ǶĒ̤Åǒ R ɉ̤ǟÀȮǿǟ ǼĒÊõǗ

Determination of water by ÀÎĒ̤ ȯǿÅõ ǦŌÅÀÛǟ ǿÅţǟ ƘĒȞǨ" ɉǟ̤ǻȝ ǨƠ ȣ̤ǒ̤ǹ ̤Ƚ Åȶõ ȸǶȞÅ :**Water** ǿÅţǟ

ȸȠ ȟ 1 ǦǟǟÀȩ ȳǼÁǬÊÅ ȗǝÅȠƳǿǟ ŌȮÎǿǟ ŌDZǗ ȸȠ Û(145 ǦǶÅÔǿǟ Û1 ǼǛǑǟ) A ǦŌÅÀÛǿǟ "the Karl Fischer method

ŌŌÅ ɍ ǗǥấÅţǟ ȸȠ ȟ 0.3 ǦǟǟÀȩ ȳǼÁǬÊÅ ǧǟǿǼĒȚǟ ȗǝÅÅǬ ŌȮÎǿǟ ŌDZǗ ȸȠ .ȟ/ȠǛȠ 10 ȸȝ ǿÅţǟ Ɂ̤ǬȚ ǼÅÂÅ ɍ ǗǥấÅţǟ

.ȟ/ȟ 0.13 ȸȝ ǼÅÂÅ ɍȘ ȟ/ȟ 0.10 ȸȝ ǿÅţǟ Ɂ̤ǬȚ

R ɉ̤ǟÀȮǿǟ ǼĒÊõǗ ȗǝÅÅǬ ȸȠ БÅʅǟ ǿÅţǟ ȸȠ ŌȠ 10 Ž ȟ 1 ǟǟǾÅ :**Acidity or alkalinity** ǦÅ̤ǛŌǿǟ ȘǗ Ǧȑ̤ȶΣǟ

(ȯ/ȯ̤Ƞ 0.1) ŌÅǿ̤ǛõȘǿǼĒȚǟ Ȑ ƥ ȸȠ ŌȠ 0.2 ȸȠ ÀǰõǗ ÆĒÛǬÅ ɍ ǗTS ȯ̤ǬÅǰǗ/ƘÅǟÅǰ̤ ȯ̤Ē̤ ȸȠ ŌȠ 0.1 ȣÅȒÅȘ

.ȯ̤Ǜɉǟ ɉ̤ǿ ƘĒȣǬǿ VS (ȯ/ȯ̤Ƞ 0.1) ȳ̤ÅấÔǿǟ ǼĒÊõȘǿǼĒȽ ȸȠ ŌȠ 0.2 ȘǗ VS

ȸÁÊÅ ÛR1 ȗDZǛǰǿǟ ŌĒǬèɉǟ Ȑ ƥ ȸȠ ŌȠ 20 Ž ÛǦĒṳ̀ǦȒȠ ǦǬȘàǹȠ Ûȟ 0.15 ǦǟǟÀȩ ǟǟǾł :**Assay** ǦÊÅÅŌţǟ

ƘǝÂøÅǟ ȯ̤ǰÅǬ-1 ȸȠ ŌȠ 0.25 ȣÅȒÅ ÛǦ̤Àȣǿǟ ǥǿǟÀǵ ǦDZǿấ ȗø̤ ấǶĒǿ õÀǬÅ Û◦ȳ50 ǥǿǟÀǵ ǦDZǿấ Ɂ øǬǵ

ɁǛȝ ȯ̤ÔΣǟ ɁøǬǵ VS (ȯ/ȯ̤Ƞ 0.1) ŌÅǿ̤ǛõƘǦǿǟ ȐȶШ ÀÅÅȞÅȘ ÛTS ŌĒǬèɉǟ Ȑ ƥ /(1-naphtholbenezein)

ǼǛǑǟ) A ǦŌÅÀÛǿǟ Ǘ"Non-aqueous titration ȗǝÅȠƳǿǟ Ùè̤ǿǟ Ž ǥÀÅÅȞţǟ" ɉǟ̤ǻȝ ǨƠ ȣ̤ǒ̤ǹ ̤Ƚ Åȶõ ÀȒǹǗ ɉ̤ǿ

.$C_6H_5Na_3O_7$ ȸȠ ȠǛȠ 8.603 ṳ̀ÅȮÅ VS (ȯ/ȯ̤Ƞ 0.1) ŌÅǿ̤ǛõƘǦǿǟ Ȑ ƥ ȸȠ ŌȠ 1 Ōõ .(142 ǦǶÅÔǿǟ Û1

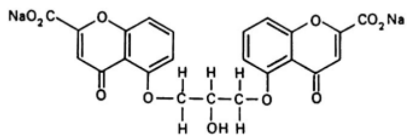
NATRII CROMOGLICAS

Sodium Cromoglicate !ǋǐǭǋȚǁ ǀǒǀǐȝǋǅǋƥǀ

$C_{23}H_{14}Na_2O_{11}$:**Molecular formula** ǦĒÅÂƨǟ ǦȣĒÔǿǟ

512.3 **:Relative molecular mass** [illegible]

:Graphic formula [illegible]



:Chemical name [illegible]

Disodium 5,5′-[(2-hydroxytrimethylene)dioxy]bis[4-oxo-4*H*-1-benzopyran-2-carboxylate]; disodium 5,5′-[(2-hydroxy-1,3-propanediyl)bis(oxy)]-bis[4-oxo-4*H*-1-benzopyran-2-carboxylate]; CAS Reg. No. 15826-37-6.

[illegible] **:Description** [illegible]

[illegible] **:Solubility** [illegible]

.R [illegible] R [illegible] TS [illegible] (750~)

[illegible] **:Category** [illegible]

[illegible] **:Storage** [illegible]

[illegible] **:Additional information** [illegible]

REQUIREMENTS [illegible]

[illegible] %98.0 [illegible] **:General requirement** [illegible]

[illegible] $C_{23}H_{14}Na_2O_{11}$ [illegible] %101.0 [illegible]

:Identification tests [illegible]

- [illegible] D [illegible] C [illegible] B [illegible] A [illegible]

Spectrophotometry in [illegible] :A [illegible] (43 [illegible] 1 [illegible]) "the infrared region [illegible] RS [illegible]

[illegible] ."Related substances [illegible] :B [illegible] C [illegible] B [illegible]

[illegible] TS1 [illegible] 4 [illegible] 3 [illegible] R [illegible] 0.5 [illegible] 5 [illegible] :C [illegible] 5

[illegible] (123 [illegible] 1 [illegible]) "General identification tests [illegible] 20 [illegible].

[illegible] 1.0 [illegible] :**Heavy metals** [illegible] 3 [illegible] "Limit test for heavy metals [illegible] (127 [illegible] 1 [illegible]) A [illegible] (128 [illegible] 1 [illegible]) 20 [illegible].

[illegible] TS [illegible] 5.0 [illegible] 20 [illegible] 0.10 [illegible] :**Oxalates** [illegible] 0.35 [illegible] 480 [illegible] 50 [illegible] R [illegible].

[illegible] 100 [illegible] :**Loss on drying** [illegible] 0.6 [illegible] 5 [illegible] 100 [illegible].

R [illegible] 25 [illegible] 1 [illegible] :**Acidity or alkalinity** [illegible] 0.1) [illegible] 0.25 [illegible] TS [illegible] 0.1 [illegible] VS (0.1 [illegible]) [illegible] 0.25 [illegible] VS ([illegible]) [illegible].

[illegible] :**Related substances** [illegible] R4 [illegible] (84 [illegible] 1 [illegible]) "Thin-layer chromatography [illegible] 9 [illegible] 10 [illegible] R [illegible] 9 R [illegible] R [illegible] 4 R [illegible] 20 (A) [illegible] 6 ([illegible] alumina [illegible] RS [illegible] 0.10 (C) [illegible] 0.10 (B) [illegible] ahead [illegible] A [illegible] 254) [illegible] B [illegible].

[illegible] 5 R [illegible] 25 [illegible] 0.18 [illegible] :**Assay** [illegible] 0.1) [illegible] R [illegible] 30 [illegible] R [illegible]-2 Non- [illegible] VS ([illegible])

0.1) ɟ̇ÊÕ̃ʒ/ Õ̃øʒÕ̃ƘǤ R̀ þ ȸ Ǭ 1 Õ̃õ .(142 ǦĦÔ Û1 ÆÕ̆) A ǦÕ̃ÛÛ"aqueous titration .$C_{23}H_{14}Na_2O_{11}$ ȸ Ʒ 25.62 ủʒ̇Ȯ VS (ȯ/ȯʒ

NATRII FLUORIDUM

Sodium fluoride !ǋǰǫǋƬǁ ǫǰþǋǂ

NaF :**Molecular formula** ǦĚÂƨ ǦȣÔ

41.99 :**Relative molecular mass** ǦĒÊ ǦĚÂƨ ǦǪȮ

.CAS Reg NO. 7681-49-4 Üÿʒá̋ʒÔ Æøʒ :**Chemical name** ȔǝĚȶĚȮ ⌊èɾ

.¢ǦĦǝø ɟ ÛR̀Ȅ ȧʒĦÊ :**Description** ƷȍʒƷ

.TS (ȯ/ȟ 750~) ȯʒǯqŽ ĚǮʒ ā̇ʂǽ Ƙɖ Ûǒȶ Ž ā̇ʂǽ :**Solubility** ǦĚǽʂØ

.Ɔ̈ÆĦ ǴȲ :**Category** ǦÂ

.ÿȮǵ ǦÕ̃ȣ ǦʂǴ Ž ÿʒá̋ʒÔ Æøʒ ȘǴ Ǣ :**Storage**ɋȸÂÅ

REQUIREMENTS ƘǦǕƘǆ!ƒ

ȸƷ ÆÂ ɟʂ %98.0 ȸƷ Õ̃Ȯ ɟ Ǭ ʔƷ ÿʒá̋ʒÔ Æøʒ Ƀʒ Ʒ :**General requirement** ÿȞ ÆÛȶ .ǦȮ ǥ̇ȶ Ƃ ţʒǲȁ ǦǽʒÊƮ NaF ȸ %101.0

:**Identification tests** ȟǐǋǈǁ ǀ ǁþƑǴǏǀ

General ǦȞ ȣȞèɾ ǧøǤǹ" ɟʒƷ Ǩ ȣʒȍʒ ʒȽ ȶõ ÿʒá̋ʒÔ ȮǲÛ ȸ øǹɾ õǲÛ ÆƷ :A ȯʒƮ R̂Ʒ ÿÆÅÊȶ ʒȽ B ȮƷ ɟõ ǽ .ǥȄư ǧƳǨ ȔÛȞ Û(123 ǦĦÔ Û1 ÆÕ̆) "identification tests .Ǭ/ȠȲ 20

1760~) Õ̃øʒȲÊ R̀ þ ȸ Ǭ 1 Ǧǟȩ ȣR̂ʂ ÛÿʒĚƳǤ ʂ î ȍ ȸ ǦÕ̃ʒ Ž ȟ 0.10 Ʒȓʒ :B ǒÛȣ ţÂø ÛǦÕ̃ȩ 15 ǥÆ Ȕ ÿþ Ž ȸÅÊʂ Ûȯʒ̇ÔǬ ȣȍ ǯǲ ǦȞÛÕ̃ ǦÕ̃ʒǤ ʔÛȣ ÛTS (ȯ/ȟ .ǨƮ ǯǲÂ ǴÛè ɟʒȮ ÜƷǲ ǴÊƺʂ ǒȶ ƷÛÎ ÛȔǲǲÂ

ǥR̂ǂ ÿʒá̋ʒÔ ȸøǟȄ ǧǫʒȍʒè ȸ Ǭ 0.10 ȸ ǰÂ Ƃ øǹɾ ǥ̇ ȸ ǧǟɖ ȔȄ ƷR̂ ȣR̂ :C .ȍ Ƃ ȯʒĦ ÛþÛ ɟʒ ǮƮ ÛTS ȮǫʒÕ̃Â ǧǫ ȸ Ǭ 0.10ʂ TS (ȯ/ȟ 10) ǲǟù

[illegible] 0.5 [illegible] **Heavy metals** [illegible]
[illegible] (127 [illegible] 1 [illegible]) 3 [illegible] "Limit test for heavy metals [illegible]
[illegible] 40 [illegible] (128 [illegible] 1 [illegible]) A [illegible]

[illegible] 10 [illegible] 130 [illegible] **Loss on drying** [illegible]

[illegible] 20 [illegible] 1.0 [illegible] **Acidity or alkalinity** [illegible]
[illegible] 0.15 [illegible] 3 [illegible]
[illegible] 1.0 [illegible] VS ($\text{ع}/\text{ع}$ 0.05) [illegible] 2.0 [illegible] TS [illegible]
[illegible] VS (0.05) [illegible]
[illegible]

[illegible] **Fluorosilicates** [illegible]
[illegible] VS (0.05) [illegible]
VS (0.05) [illegible] 1.5 [illegible]

[illegible] 15 [illegible] 1.0 [illegible] 30 [illegible] **Assay** [illegible]
[illegible]
[illegible] VS (0.1) [illegible] Reflux condenser
(142 [illegible] 1 [illegible]) A [illegible] "Non-aqueous titration [illegible]
NaF [illegible] 4.199 [illegible] VS (0.1) [illegible] 1 [illegible]

NATRII NITRIS

Sodium nitrite [illegible]

$NaNO_2$ **:Molecular formula** [illegible]

69.00 **:Relative molecular mass** [illegible]

CAS Reg. NO. 7632-00-0 [illegible] **:Chemical name** [illegible]

[illegible] **:Description** [illegible]
[illegible]

Solubility: (~750) TS.

Category:

Storage:

Additional information:

REQUIREMENTS

General requirement: %98.0 … %100.5 $NaNO_2$.

Identification tests:

A: … "General identification tests" (… 123 …) … B … 0.10 … (~300) TS.

B: … 0.10 … 1 … 1.0 … (~15) TS …

C: … 0.20 … 1 … 1.0 … (~100) TS … TS …

Heavy metals: … 1.0 … 10 … (~70) TS … "Limit test for heavy metals … 1 … (… 128 …) A … (127 … 20 …

Chlorides: … 2.5 … 3 … 2 … (~1000) TS … "Limit test for chlorides" (… 124 …) … 0.1 …

Loss on drying: … R … 4 … 5.0 …

[illegible] 0.1 [illegible] 10 [illegible] 0.5 [illegible] :**Acidity or alkalintiy** [illegible]
[illegible] 0.3 [illegible] 0.25 [illegible] (0.01 [illegible]) [illegible]
[illegible] (0.01 [illegible]) [illegible]

[illegible] 100 [illegible] 0.4 [illegible] :**Assay** [illegible]
[illegible] 10 [illegible] (0.02 [illegible]) [illegible] 20 [illegible] 10.0
[illegible] swirl [illegible] 0.5 [illegible] 10 [illegible] (1760~ [illegible])
[illegible] (0.1 [illegible]) [illegible]
[illegible] $NaNO_2$ [illegible] 3.450 [illegible] (0.1 [illegible]) [illegible]

[illegible]

Additional Requirements for Sodium nitrite for parenteral use

[illegible] "*Parenteral preparations* [illegible]" [illegible] (56 [illegible] 4 [illegible]).

[illegible] :**Bacterial endotoxins** [illegible]
"Test for Bacterial endotoxins [illegible]" (5 [illegible] 30 [illegible])
[illegible] 0.33 RS [illegible].

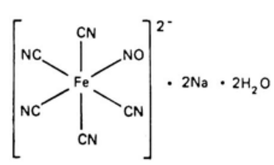
NATRII NITROPRUSSIDUM

Sodium nitroprusside [illegible]

$Na_2[Fe(CN)_5NO],2H_2O$:**Molecular formula** [illegible]

298.0 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

Disodium pentacyanonitrosylferrate(2–) dihydrate; disodium (*OC*-6-22)-pentakis(cyano-*C*)nitrosylferrate(2–) dihydrate; CAS Reg. No. 13755-38-9 (dihydrate).

[illegible] :**Other names** [illegible]

[illegible] :**Description** [illegible]

[illegible] :**Solubility** [illegible] TS (~750) [illegible]

[illegible] R [illegible]

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

REQUIREMENTS [illegible]

[illegible] :**General requirement** [illegible] %99.0 [illegible] %100.5 [illegible] $Na_2[Fe(CN)_5NO]$ [illegible]

:**Identification tests** [illegible]

A: [illegible] 4 [illegible] 350 [illegible] 600 [illegible] 395 [illegible] 1 [illegible] 1.10 [illegible]

B: [illegible] General [illegible] "identification tests" (123 [illegible] 1 [illegible]) [illegible] B [illegible] 0.10 [illegible] TS (~300) [illegible]

C: [illegible] 5 [illegible] 2.0 [illegible] 1 [illegible] R [illegible] 0.5 [illegible] (~80) [illegible] TS (~130) [illegible] 2 [illegible] TS (~300) [illegible]

[illegible] :**Chlorides** [illegible] 1.20 [illegible] 2 [illegible] TS (~130) 30 [illegible] "Limit test for chlorides" [illegible] (124 [illegible] 1 [illegible]) [illegible] 0.2 [illegible]

[illegible] :**Sulfates** [illegible] 5.0 [illegible] 40 [illegible] "Limit test for sulfates" (125 [illegible] 1 [illegible]) [illegible] 0.1 [illegible]

[illegible] :**Ferricyanide** [illegible] 0.50 [illegible] 20 [illegible] 4.62 TS [illegible] A [illegible] B [illegible] 1 [illegible] (50 [illegible]) [illegible] 5 [illegible] TS (1) [illegible] 50 [illegible]

50 БǗ ǒǺţǺǽ ƵȦơş ÛTS Û4.62 ǒǺŁǺǽ Û Ûÿ̄ƶǃǫƶŋǰ̈ ǧǺǬƎèǗ Ǧəǿǟǻ ȸŋ Ōŋ 10 Ž Ǧòƶ ǶǺţǟ ǥǻǺţǟ ȸŋ ȟ0.25 Ǧǟǟǽǚǽ
ɟƶȮǺ ɍ .ǺǦǺǺŌǩ ǺǬŋƶǫǺǫ 720 ǦDZƶŋ ȯƶǜ ǼǺȝ ɄȶŢȝǰ̈ ȻǼǵ Ž î ǺȶǬǟ âǺŌǺş ǥǼǵǟş Ǧȝǻè ǥǼŋ ǺŌǬÊǬǒ ǒǺǬǩ .Ōŋ
.(ȟ/ŋǛŋ0.2) A ǒÂƨǟ ŌǟǺŌŋ âǺŌǺ ǺŋǼǺȝ B ǒÂƨǟ î ǺǬ ȸŋ ƎõǗ ǼŁǺÎǟ ŌǟǺŌŋ âǺŌǺ ǺŋǼǺȝ A ǒÂƨǟ î ǺǬ

ȣǺȒǺ .Bş A ƙǺşǺÊǬŋ ƙəÂDZ БǗ ȯƶǛǂǟ ǺǺDZǺş ǒǺţǟ ȸŋ Ōŋ 40 Ž ȟ 2 ǟǟǾǺ :**Ferrocyanide** ǼƎǫǺƎèşƘƶ
ȸŋ Ōŋ 0.2 ƙəÂƨǟ ƔõБǗ ȣǺȒǺ Ż ÛTS (Ōŋ/ÿǟǺȡşǺŌŋ 100) ɃǿǺƎǶţǟ ǼƎǫǺƎèşƘǺǟ ȸŋ Ōŋ 2 B ǒÂƨǟ БǗ
Ǧǟǟǽǚǽ ǼŁǺì ȯƶǛŢ ǺȒȜ .ȨəǺȩǻ 5 ǥǼŋ ǺŌǬÊƎǒ ǒǺǬǺ .Ōŋ 50 БǗ ǒǺţǺǽ ƵȦƸş TS (ȯ/ȟ50) ȬǺǼǺǼΣǟ ǼǺǿƶǛõ
ǺǬŋƶǫǺǫ 695 ǦDZƶŋ ȯƶǜ Ž ɄȶŢȝǰ̈ ȻǼǵ ǼǺȝ î ǺȶǬǟ âǺŌǺ .Ōŋ 50 ǯǺǬǫq ȣǺõ ǒǺŋ Ž Ǧòƶ ǶǺţǟ ǥǻǺţǟ ȸŋ ȟ1.0
0.2) A ǒÂƨǟ ŌǟǺŌŋ âǺŌǺ ǺŋǼǺȝ B ǒÂƨǟ î ǺǬ ȸŋ ƎõǗ ǼŁǺÎǟ ŌǟǺŌŋ âǺŌǺ ǺŋǼǺȝ A ǒÂƨǟ î ǺǬ ɟƶȮǺ ɍ .ǺǦǺǺŌǩ
.(ȟ/ŋǛŋ

30 ǥǼŋ ɄəǺŋ ÿǺƥ ɂǛȝ ȯƶǛǂǟ ȸǺÊǺ ÛǒǺţǟ ȸŋ Ōŋ 50 Ž ȟ10.0 ǟǟǾǺ :**Insoluble matter** ǦǟşǾǟ Ƙȡ ǥǻǺţǟ
ǥǻǺţǟ ɁƶǬŢ ǼǺÂǺ ɍ Û°ÿ105 ǦDZǿǼǟ ǼǺȝ ǨǟǺǫ ɟàş ɂøǬǵ ƵȦθş ÛǒǺţǺǽ ǦǟşǾǟ Ƙȡ ǥǻǺţǟ ŌÊȣǩ ÛǴìǺǺ ÛǦŌƎȩǻ
.ȟ/ŋǛŋ 0.1 ȸȝ ǦǟşǾǟ

Determination of water by ǺÎƎƶ ȯǿǺõ ǦŌǺǺÛǽ ǒǺţǟ ƙƎǨǩ" ɟǟƶǺȝ ǨƠ ȣƶòƶŋ ƶŁ ǺȶõȸǺǨǺ :**Water** ǒǺţǟ
ǒǺţǟ ɁƶǬŢ ŌŌǺ ɍ ÜǥǻǺţǟ ȸŋ ȟ 1 ǦǟǟǺȩ ÿǼǺǬÊǺ Û(145 ǦǶǺÔǟ Û1 ǼǛŎǟ) A ǦŌǺǺÛǟ "the Karl Fischer method
.ȟ/ŋǛŋ 150 ȸȝ ǼǺÂǺ ɍş ȟ/ŋǛŋ 90 ȸȝ

ȐƥȸŋŌŋ 0.1 ȣǺȒǺ .ǒǺţǟ ȸŋ Ōŋ 100 Ž ÛǦƎǜƶǦȒŋ Ǧǫşàƶŋ Ûȟ0.35 ǦǟǺȩ ǟǟǾǺ :**Assay** ǦÊǺǺŌţǟ
ƙǨǩ ÛVS (ȯ/ȯƶŋ 0.1) ǦȒǺǟ ǧǟǺǬǺǽ ǺǺǺǨǺ .TS (ȯ/ȟ750~) ȯƶǫǺǯǺqǟ ȸŋ Ōŋ 20ş TS (ȯ/ȟ100~) ȬǺǿƶǺǛÊǟ
ǧǟǺǬǫ ȸŋ ǺǬǒ ɄǛƎŋ Ǽǵǟş Ōõ .ǦȒǺǟ ǼǺǿƶǛõ/ǦȒǺǟ ɄøǟǺȾȮǟ ɁǺÊţǟ ÿǺŢǫ ÿǟǼǺǬèǺǽ ǼȾƨǟ âǺƎŌŋ ǦǺǺȾǺǟ ǦÛŌǫ
.Na$_2$[Fe(CN)$_5$NO] ȸŋ ŋǛŋ 13.10 ǜƶǺȮǺ VS (ȯ/ȯƶŋ 0.1) ǦȒǺǟ

NATRII STIBOGLUCONAS

Sodium stibogluconate !ǌǐǫǋŢǁǀ ǀǂǄǌǀǌǂȜǌǦǏƨ

.ǼƎõǺǬǟ ȸǺǨŋ Ƙȡ ǘƶǺȮǬǟ ɄèǺȒ ɟǟƶȶǬǗ ǼõǺŋ ƶŁ ÿƶǺǻƶÔǟ ǧǺǫƶõƶǛȡ ƶǦǬè :**Composition** ǼƎõǺǬǟ
.ɟǟƶȶǬǗ ǥǿǽ ŌÖǒ ÿƶǺǻƶò ǥǿǽ 2 ȸŋ ŌȩǗ ǥǻǺȝ ɃƶǬȜ ȼǺȮǒş ÛC$_6$H$_9$Na$_2$O$_9$Sb ǦȣƎÔǒǺǽ ŌǯƩ

[illegible] **:Chemical name**

D-Gluconic acid cyclic ester with antimonic acid ($H_8Sb_2O_9$) (2:1), trisodium salt, nonahydrate; 2,4:2′,4′-*O*-(oxydistibylidyne)bis-D-gluconic acid, *Sb,Sb′*-dioxide, trisodium salt, nonahydrate; CAS Reg. No. 16037-91-5.

[illegible] **:Description** [illegible].

[illegible] **:Solubility** [illegible] (~750 [illegible]) TS [illegible] R.

[illegible] **:Category** [illegible].

[illegible] **:Storage** [illegible].

REQUIREMENTS [illegible]

[illegible] **:General requirement** [illegible] 30.0% [illegible] 34% [illegible].

[illegible] **:Identification tests**

A: [illegible] (~60 [illegible]) TS [illegible] General [illegible] "identification tests [illegible] 1 [illegible] 123).

B: [illegible] 0.5 [illegible] 10 [illegible] TS [illegible] (~80 [illegible]) TS.

C: [illegible] 10 [illegible].

[illegible] **:Chlorides** [illegible] 2.5 [illegible] 50 [illegible] 2 [illegible] (~130 [illegible]) TS [illegible] 75 [illegible] 5.0 TS. [illegible] (0.1 [illegible]) VS [illegible] Potentiometrically [illegible] 3.0 [illegible] (0.1 [illegible]) VS.

[illegible] **:Loss on drying** [illegible] 130° [illegible] 6 [illegible] 5 [illegible] 150 [illegible].

[illegible] **:Colour and pH value** [illegible] 0.3 [illegible] 10 [illegible] 70 [illegible] 30 [illegible] 5.0 [illegible] 5.6.

[illegible] 15 [illegible] 30 [illegible] 2.0 [illegible] : **Trivalent antimony** [illegible] TS [illegible] VS (ò/òz 0.00833) [illegible] TS (ò/h250~) [illegible] .VS (ò/òz 0.00833) [illegible] 1.3 [illegible]

[illegible] 10 [illegible] 300 [illegible] 0.25 [illegible] :**Assay** [illegible] TS (ò/h1760~) [illegible] 5 TS (ò/h1000~) [illegible] 1 [illegible] h1 [illegible] TS (ò/h1000~) [illegible] 60 R [illegible] h1 [illegible] 5 [illegible] R [illegible] h1 [illegible] 15) [illegible] TS (ò/h400~) [illegible] TS (ò/h100~) [illegible] TS [illegible] VS (ò/òz 0.02) [illegible] R [illegible] 2.435 [illegible] VS (ò/òz 0.02) [illegible].

NATRII SULFAS

Sodium sulfate [illegible]

$Na_2SO_4.10H_2O$:**Molecular formula** [illegible]

322.2 :**Relative molecular mass** [illegible]

:**Chemical name** [illegible]

Disodium sulfate decahydrate; sulfuric acid disodium salt, decahydrate; CAS Reg. No. 7727-73-3 (decahydrate).

[illegible] :**Other name** [illegible]

[illegible] :**Description** [illegible]

.TS (ò/h750~) [illegible] :**Solubility** [illegible]

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]
.[illegible] 30 [illegible]

[illegible] :**Additional information** [illegible]
.[illegible] 33

REQUIREMENTS [illegible]

[illegible] :**General requirement** [illegible] 99.0% [illegible] 100.5% [illegible] Na_2SO_4 [illegible].

:**Identification tests** [illegible]

A: [illegible] "General identification tests" [illegible] (123 [illegible] 1 [illegible]). [illegible] B [illegible] 0.05 [illegible].

B: [illegible] 0.05 [illegible] A [illegible] "General identification tests" [illegible] (123 [illegible] 1 [illegible]).

:**Heavy metals** [illegible] 1.0 [illegible] "Limit test for heavy metals" [illegible] 1 (127 [illegible] 1 [illegible]) [illegible] A (128 [illegible] 1 [illegible]) [illegible] 20 [illegible].

:**Ammonium salts** [illegible] 1 [illegible] 0.3 [illegible] R [illegible] R [illegible].

:**Arsenic** [illegible] 5 [illegible] 35 [illegible] "Limit test for arsenic" [illegible] (130 [illegible] 1 [illegible]) [illegible] 2 [illegible].

:**Calcium** [illegible] 0.2 [illegible] (100 [illegible] 1.5 [illegible] (25 [illegible]) TS [illegible] (Ca [illegible] TS [illegible] 1 [illegible] (~120 [illegible]) TS. [illegible] 15 [illegible] 10 [illegible] (100 [illegible] Ca) TS [illegible] 0.5 [illegible] 15 [illegible] 5 [illegible]

.(ȟ/ÿǟÀȡşÀȮɳ 200) ɄøɸǰǍ ǟ ɀǫɉǟ Ž

Ȭɳ 30ş TS (ȯ/ȟ130~) ȬȦȦǢǓ Ȑƥ ȸɳ Ȭɳ 2 ȸɳ Ȥǘǘɳ ǰȦȦɳ ȸɳ ȟ1.25 ǟǟǾ :**Chlorides** ǧǟǼǾȥŸȮǟ ǼŸȮǟ) "Limit test for chlorides ǧǟǼǾȥŸȮǟ ȬǱɉ ɃǼƩǟ øȦǪȵɍǟ" ɉǟȥ3 ȞƠ ȢȥȍȥɳȥȽ ȦȽȭ ȝǟǪş ǒȦȶǟ ȸɳ .ȟ/ȠŸɳ 0.2 ȸɳ ǍǰȭǙ ǼǾȥŸȮǟ ʡȥǪȚ ɉȥȮ ɍ Ǚ(124 ǦȟȦȎǟ Ǚ1

øȦǪȵɍǟ" ɉǟȥ3 ȞƠ ȢȥȍȥɳȥȽ ȦȽȭ ȝǟǪş ǙǒȦȶǟ ȸɳ Ȭɳ 40 Ž ȯȥŸȚ ǨȒȟǪ ȟ1.0 ÿǼǺǪȄ :**Iron** ǼǼƩǟ .ȟ/ÿǟÀȡşÀȮɳ 40 ȸ3 ǼǍǍ ɍ Ǚ(129 ǦȟȦȎǟ Ǚ1 ǼŸȮǟ) "Limit test for iron ǼǼƩ ȬǱɉ ɃǼƩǟ

ǧǍǍȍ ȸɳ Ȭɳ 0.15ş R ȯşǨȆǼŸȢǟ ȸɳ Ȭɳ 1 ȢǍȐǪş ǙǒȦȶǟ ȸɳ Ȭɳ 10 Ž ȟ0.5 ǟǾ :**Magnesium** ÿȥǍǼȢȶǟ ÿȥǻȥȎǟ ǼǼȆȭşøǼȽ ȸɳ Ȭɳ 5ş TS (ȯ/ȟ50) ÿȥǪȥɳɉǟ ǧɍǟǍȭşǙ ȸɳ Ȭɳ 0.2ş TS Titan yellow ɉǪǪǟ 5 ȸɳ ɉȥȮɳş ȬǪǍư ȥǙ ʡŸ3 Ȭɳȥ3 ǰǍǍɳ ɉȥǟ ȸɳ ǧǼȉ ǍǰȭǙ ɉȥȮǍ ɍ ǰǪǍ ɄŸǍɸǍȩ ɉȥǟ ɃǙ Ǚǯǰş ǙTS (ȯ/ȟ80~) .ǒȦȶǟ ȸɳ Ȭɳ 5ş TS (Mg Ȭɳ/ÿǟÀȡşÀȮɳ 10) ɃøǼȟȶǟ ÿȥǍǼȢȶǟ ȸɳ Ȭɳ

ɄȧǍǪ ȸɳ ƃǍǙǟ ǒȦȶǟ ȸɳ Ȭɳ 10 Ž ȟ0.50 ȯȥŸȚ ɉȥȮǍ :**Clarity and colour of solution** ȯȥŸǂǟ ɉȥǟş ǒǍȍ .ǘ ɉȥǟ ɍş ȢǍȍ R ɉȥǟǍȮǟ ǼǼȆȭǙ

ȬǾȥǍŸȆǟ Ȑƥ ȸɳ Ȭɳ 1 ȢǍȐǍ ǙǒǍɳ Ȭɳ 5 Ž ȟ0.5 ǟǾ :**Reducing substances** ǦǟǍǺȶǟ ǻǟȥȶǟ ŞǧŸǍ ɍ ǙǦȬǼȩǻ 15 ǧǼɳ ǍȬǪȆǼ ȭǍǪ .VS (ȯ/ȯȥɳ 0.002) ÿȥǼȅǍȥǦǟ ǧǍǍȢǍɳǨǟ ȸɳ Ȭɳ 0.20ş TS (ȯ/ȟ100~) .discoloration ɉȥŸǟ Ž (ȯǟşǟ) ȯǼǦ ɃǙ

Ǽ3 ȞǟǰǍ ɉǟȥǟ ƃǙ Ż ǧǼǧǟş Ǧ3ǍȅǧǼɳ °ÿ30 ǧøǟǍǧ ǦǱøǻ Ǽ3 ȤǍƶ :**Loss on drying** ȤǼǍǱȢǍǍǟ ǼȬǍǟ .ȟ/ȟ0.57 ȸ3 ǼǍǍ ɍş ȟ/ȟ0.52 ȸ3 ǼȬǍǟ ȬȬǍ ɍ Ǚ°ÿ130 ǧøǟǍǧ ǦǱøǻ

ɉȥǟǍȮǟ ǼǼȆȭǙ ɄȧǍǪ ȸɳ ƃǍǙǟ ǒȦȶǟ ȸɳ Ȭɳ 10 Ž ȟ0.5 ǟǾ :**Acidity or alkalinity** ǦǍȥŸȬǟ şǙ ǦȑȥȽƩǟ ÿȥǻȥȎǟ ǼǼȆȭşøǼȽ ȸɳ Ȭɳ 0.5 ȸɳ ǍǰȭǙ ǼŸǛǍ ɍ ǙTS ȯȥɸǰǙ/ ȯȥȽǼȥɳşƎǟ Ǧȩøǟ ȸɳ Ȭɳ 0.1 ȢǍȐǍş R Ȑƥ ȸɳ Ȭɳ 0.5 şǙ VS (ȯ/ȯȥɳ 0.01) carbonate-free sodium hydroxide ǧǍɸȥǍȮǟ ȸɳ ƃǍǙǟ .(ǍȐȵǙ) ǍȞȊȽǙ ʡǛȅȥǟ ǦǛȬǍǟ ʡŸ3 ȯȥȎȟǙ VS (ȯ/ȯȥɳ 0.01) ȬǾȥŸȭşøǼȚǟ

Ȑƥ ȸɳ Ȭɳ 10 ȢǍȐǍş ǙǒȦȶǟ ȸɳ Ȭɳ 250 Ž ǙǦǼùȥǦȐȠ ǦɸşǍȥɳ Ǚȟ0.25 ǦǟǍȩ ǟǾ :**Assay** ǦȆǍȬȶǟ .TS (ȯ/ȟ50) ÿȥǍøǍǦǟ ǼǾȥŸȭ ȸɳ ǦǼȥǍȭ ǦȽȭ ȢǍȐǍş ɉǼŸȢǟ ʡøǪǧ ȸǺȆǍ ǙTS (ȯ/ȟ70~) ȬǾȥŸȭşøǼȚǟ ǧøǟǍǧ ǦǱøǻ Ǽ3 ǼȠǍǍş ȤǍƟ ǙȬȆȢǨ ǙǦǟǍȅǍǟ 3ȽƟ .ǍɸǼǧǙ ȬǍǍȟǪǟ 3ɳ ǙǦȬǼȩǻ 30 ǧǼɳ ɄȧǍɳ ÿǍƥ ʡŸ3 ȸǺȆǍ .°ÿ600 ȬȭǍ ǍǟǍȡ ÿǍǍȡ ǧǼǧǟş ÿǟǍȡ Ȭȭ .Na_2SO_4 ȸɳ ȟ0.608 ùȥǍȮǍ ǦǟǍȽǰǟ ȸɳ ǼǧǟȘ

NATRII SULFAS ANHYDRICUS

Sodium sulfate, anhydrous ƽŏƏƑDŽǘǁƐ !ǊŏơǊTǁƐ ƖƑƸǂƨ

Na_2SO_4 **:Molecular formula** ǦƐÅÂƨǎ Ǵ8ƐÔǎ

142.0 **:Relative molecular mass** ǦƐǤÊǺǎ ǦƐÅÂƨǎ ǦŸǪÒǎ

:Chemical name ƱƏÅƐȶƑÒǎ ǈèɍǎ

Disodium sulfate; sulfuric acid disodium salt, anhydrous; CAS Reg. No. 7757-82-6 (anhydrous).

.ǦƜƏäÀǎ ƇǼƷ ǓȐƐǕ ȧƺƜÊƞ **:Description** Ȥòƺǎ

.TS (ȯ/ȟ750~) ȯƺǪǮǪqǎ Ž ǼŸȶƷ āǎşǽ Ƙȡ ǗǑÅţǎ Ž ȷǼşØǎ ǺǵǾ **:Solubility** ǦƐşØǎ

.ȸȹŸƞ **:Category** ǦÅÅǎ

.ǼǼƐDZ ǦǑŸ8ƞ ǦǺşǺǵ Ž ǦƐƏǺƞŸǎ ȳƺǺǻƺÔǎ ǧǺŸè ȘǺǵ Ǣƶ **:Storage**ǭȸǺÂÅǪǎ

.ǦǦùÀǪÊƞ ǥǻƞ ǦƐƏǺƞŸǎ ȳƺǺǻƺÔǎ ǧǺŸè **:Additional information** ǦƐƺǺȑǓ ǧǺƞƺŸȞƞ

REQUIREMENTS ƘǦǓƱǩdž!ƒ

ǼÂÂǺ ɍş %99.0 ȸƷ ŌŌǺ ɍ Ǻƞ ɁŸƷ ǦƐƏǺƞɍǎ ȳƺǺǻƺÔǎ ǧǺŸè ȸƺǪƠ **:General requirement** ȳǺȞǎ ǼŸÛǪţǎ .ǦƺǺƨǎ ǥǻǺţǎ БǗ ţƺDZÀǎǼǽ ǦǽƺÊƮ ÛNa_2SO_4 ȸƞ %100.5 ȸƷ

:Identification tests ƽŏǋǊǁƐ ƖƐƥƑǴƢƐ

General ǦƞǺȞǎ 8ǎȞǪèɍǎ ǧǎøǺǪǹǎ" ȷǎƺǺƷ ǨƠ 8ƺòƺƞ ƺȽ ǺȶÕ ȳƺǺǻƺÔǎ ŌDZǓ ȸƞ øǺǪǹɍǎ ǼǺƷ :A 20 ȯƺŸƮ ȀȒƷ B ŌƷǺǺǪǎ ȳǼÅǪèǎ ǎǽǓ .ǥǺƐư ǧŸƷǺǺǩ ƱÛȞǺ (123 ǦƜȦÔǎ Û1 ǼŸǑǎ) "identification tests .Ōƞ/ƞŸƞ

General ǦƞǺȞǎ 8ǎȞǪèɍǎ ǧǎøǺǪǹǎ" ȷǎƺǺƷ ǨƠ 8ƺòƺţǎ A ŌƷǺǺǪǎ Ōƞ/ƞŸƞ 20 ȯƺŸƮ ƱÛȞǺ :B .(123 ǦƜȦÔǎ Û1 ǼŸǑǎ) ǧǺŸÊŸǒ ǺƐȶȶÕ "identification tests

ȷǎƺǺƷ ǨƠ 8ƺòƺƞ ƺȽ ǺȶÕ øǺǪǹɍǎ ȯƺŸƮ ƘȒƠ ŌDZǓ ȸƞ ȟ0.5 ȳǼÅǪÊǺ **:Heavy metals** ǦŸƐŌǯǎ ȷǻǺȞţǎ ȸȹȞǩ Ǘ(127 ǦƜȦÔǎ Û1 ǼŸǑǎ) 1 ǒǎȀDZqǎ "Limit test for heavy metals ǦŸƐŌǯǎ ȷǻǺȞţ ŌDZɉ ɃǼΣǎ øǺǪǹɍǎ" .ȳǎȀȡ/ȳǎȀȡşÀǑƞ 45 ȸƷ ǼÂÂǩ ɍ Ǘ(128 ǦƜȦÔǎ Û1 ǼŸǑǎ) A ǦŌȀÛŸǒ ǺǴǦǩ ǦŸƐŌǯǎ ȷǻǺȞţǎ ǧǺƺǪƮ

ǼƐÊÕşøǼƐȽ ȸƞ ȟ0.3 ǦǽǎǺę 8ÅȒǺ ÛøǺǪǹǎ āƺǦǪǓ БǗ ȟ0.5 ŌŌǺǺ **:Ammonium salts** ȳƺƐǪƺƞɉǎ ǳŸƞǓ

Arsenic: 2.0 ... 35 ... "Limit test for arsenic ... (130 ... 1) ... 5 ...

Calcium: 0.2 ... 100) ... (Ca ... 1.5 ... TS (25 ...) ... TS (~120) ... 1 ... (Ca ... 10) ... 10 ... 15 ... 0.22 ... 15 ... 5 ... (450) ...

Chlorides: 0.55 ... 2 ... TS (~130) ... 30 ... "Limit test for chlorides ... (124 ... 1) ... 0.45 ...

Iron: 0.44 ... 40 ... "Limit test for iron ... (129 ... 1) ... 90 ...

Magnesium: 0.22 ... 10 ... 1 ... 0.15 ... TS Titan yellow ... 0.25 ... TS (50) ... 5 ... TS (~80) ... (Mg ... 10) ... 5 ... 5 ...

Clarity and colour of solution: 0.22 ... 10 ...

Reducing substances: 0.25 ... 5 ... 1 ... TS (~100) ... 0.20 ... (0.002) VS ... 15 ... discoloration ...

Loss on drying: 130 ... 50 ...

Acidity or alkalinity: 0.22 ... 10 ...

ÿɀɅǻɀÔöä ǼɆÊȭşøǼɆȽ ȸɳ Ǿɳ 0.5 ȸɳ ÀǯȭǗ ǼŸÛɊ ɟ ǗTS ȯɀɊǯǗ/ ȯɀȶɆɀɳşɅöä Ǧęøǟ ȸɳ Ǿɳ 0.1 ȣÂŘɅş R
Ȁþ ȸɳ Ǿɳ 0.5 şǗ VS (ȯ/ȯɀɳ 0.01) carbonate-free sodium hydroxide ğɊɀæÀȮöä ȸɳ БÂʅä
.(ÀŘǹǗ) ÀĦÎȶŸö ʔÛèɀöä ǦÛȭɊöä ʔŸȝ ȯɀÔȞŸö VS (ȯ/ȯɀɳ 0.01) ȭɊøɀŸȭşøǼɆTä

Ȁþ ȸɳ Ǿɳ 10 ȣÂŘɊ ÛöÂţä ȸɳ Ǿɳ 250 Ž ÛǦɆùɀǦŘɳ Ǧɸşàɀɳ Ûȟ0.1 Ǧæ̈Âę ąäØɊ :**Assay** ǦÊɊÂȭţä
.TS (ȯ/ȟ50) ÿɀɊøÂǦöä ǼɊøɀŸȭ ȸɳ ǦɆɀÂȭ ǦɆȶȭ ȣÂŘǩş ÛɈÂɆŸȣöä ʔøɊğ ȸǺÊɊ ÛTS (ȯ/ȟ70~) ȭɊøɀŸȭşøǼɆTä
.ÿ 600 ğøäÀğ ǦǱøǻ ǼɊȝ ǼɳÀǩş ȤÂƟ ÛȬÊȣǩ ÛǦæÂèÀöä ȝȶƟ .ǺɊÂɆğǗ ȭÀȜ ÛǦȭɆęǻ 30 ğǼɳ ȺȤÂɳ ÿÂþ ʔŸȝ ȸǺÊɊ
.Na_2SO_4 ȸɳ ȟ0.608 øö ùɀÂȮɊ ǦöÂȶǯöä ȸɳ Ǽğäş ÿäÀȡ Ȫȭ

NATRII THIOSULFAS

Sodium thiosulfate !ǋǰǭǋȚǁ ȴȥǂɂǋǰǩ

$Na_2S_2O_3,5H_2O$:**Molecular formula** ǦɆÂɊÂɂä ǦȣɆ Ôöä

248.2 :**Relative molecular mass** ǦǦÊɊöä ǦɆÂɊÂɂä ǦŸɊȮöä

:**Chemical name** ȺəÂɆȶɆȮöä ʅèɟä

Disodium thiosulfate pentahydrate; disodium thiosulfate ($Na_2S_2O_3$) pentahydrate; thiosulfuric acid ($H_2S_2O_3$), disodium salt, pentahydrate; CAS Reg. No. 10102-17-7 (pentahydrate).

.ǦȺəäÀöä ǦɌǼȝ ÛɅɀŸöä ǦɌǼȝ ǦɀÂÀɩ ğäøɀŸæ :**Description** Ȥȍɀöä

.TS (ȯ/ȟ750~) ȯɀɊǯɊqä Ž ÂɆŸȶȝ ąäşæ Ƙȡ ÛöÂţä Ž ÂǼǱ ąäşæ :**Solubility** ǦɊÂæşØöä

.ȧÂɊøǻ :**Category** ǦÂÂöä

.ÿÂȮğüæ ǦȭŸȣɳ ǦɊşÂğ Ž ÿɀɅǻɀÔöä ğÂÂŸèɀɆɊ ȘÂğ Ǽʑ :**Storage**ȹȸɊÂǺɊöä

ǦǱøǻ Ž ȣÂɂä öäɀTä Ž ÿɀɅǻɀÔöä ğÂÂŸèɀɆɊ ğäøɀŸæ ÀȽÂɊǩ :**Additional information** ǦɆɀÂȓǗ ğÂɳɀŸȞɳ
.ÂǦɊÀȭǩ °ÿ 49 ǦǱøǼöä Ž ÂȽøɀŸǦǩ öÂɳ Ž ąşØǩş °ÿ33 ȸȝ ǼɊÂǩ ğøäÀğ

REQUIREMENTS ƘǦȞȽƱǩǅ!ƒ

ȸȝ ǼɊÂɊ ɟş %99.0 ȸȝ ȬȭɊ ɟ Âɳ ʔŸȝ ÿɀɅǻɀÔöä ğÂÂŸèɀɆɊ ɃɀɊƠ :**General requirement** ÿÂȞöä ǼŸÛɊţä
.$Na_2S_2O_3,5H_2O$ ȸɳ %101.0

[illegible] :Identification tests

1.0 [illegible] 10 [illegible] :A

[illegible] 50 [illegible] 0.25 [illegible]

[illegible] 70~ [illegible] 1.0 A [illegible] 2 [illegible] :B

[illegible]

[illegible] 0.1 [illegible] 2 A [illegible] 2 [illegible] :C

[illegible]

[illegible] :D

[illegible] B [illegible] (123 [illegible] 1 [illegible]) "General identification tests

[illegible] 0.10

[illegible] 5 [illegible] 10 [illegible] 1.0 [illegible] :**Heavy metals** [illegible]

[illegible] 15 [illegible] 70~)

[illegible]

[illegible] 0.05 [illegible]

[illegible] 4-3 [illegible] VS [illegible] 1) [illegible] TS [illegible]

[illegible] 40 [illegible] 60~)

[illegible] (128 [illegible] 1 [illegible]) A [illegible] "Limits test for heavy metals [illegible]

[illegible] 20

[illegible] 130~) [illegible] 20 [illegible] 1.20 [illegible] :**Chlorides** [illegible]

[illegible] 4-3 [illegible] TS

[illegible] 0.2 [illegible] (124 [illegible] 1 [illegible]) "Limit test for chlorides [illegible]

TS [illegible] 5 [illegible] 10 [illegible] 0.25 [illegible] :**Sulfates and sulfites** [illegible]

[illegible] TS [illegible]

[illegible] (125 [illegible] 1 [illegible]) "Limit test for sulfates [illegible]

[illegible] 2 [illegible]

sodium [illegible] 0.05 [illegible] 10 [illegible] 1 [illegible] :**Sulfides** [illegible]

[illegible] TS [illegible] 45) nitroprusside

R ȷɀǟÀȮǚǟ ǼĿÊõǕ ȜəǺǺǫ ȡȠ ƃǺʅǟ ǒǺʈǟ ȡȠ ǬȠ 10 Ž ȟ1.0 ȯɀŶʅ ȷɀȮǺ :**Clarity and colour** ȷɀŶǚǟş ǒǺǺÔǚǟ
.¢ǚ ȷɀǚ ɾş ȣǺǒ

.8.4-6.0 ÛR ȷɀǟÀȮǚǟ ǼĿÊõǕ ȜəǺǺǫ ȡȠ ƃǺʅǟ ǒǺʈǟ Ž Ǭȡ/ȟ0.10 ȯɀŶʅ ǒǺĿǺǟ :**pH value** ǒǺĿǺǤǚǟ ǤȴĿę

0.05) iodine ǻɀĿǚǟ ȝȠ ǺǺȞǺş ǒǺȠ ǬȠ 25 Ž ÛǦĿùɀǤȒȠ ǤǫşàɀȠ ÛȟO.5 ǤǟǟǺę āǟØǺ :**Assay** ǤÊǺǺÕʈǟ
ùɀǺȮǺ VS (ȯ/ȯɀȠ 0.05) ǻɀĿǚǟ ȡȠ 1 Ǭõ .ǥǺǺȞʈǟ ǤǺǺŒ ɀǓ ȣǺȒǺ .ǺȞÎȴõ TS ǺÎǺǚǟ ÿǟǼǺǫèǺǟ VS(ȯ/ȯɀȠ
.$Na_2S_2O_3,5H_2O$ ȡȠ ȝȠ 24.82

ǿǚşƟ üǷǅƴƚƨǗɛ üɰǓ !ǋǰǡǋƬǁɛ ǀǷƻƨǋǰǁ ȟǰȢǷƮǻ ǀǷǤǂƯǄǅ

Additional Requirements for Sodium thiosulfate for parenteral use

.(56 ǤȞǺÔǚǟ Û4 ǼŶǑǟ) "*Parenteral preparations* ǤǼǺȬΣǟ ğǟǺȒȞǫÊʈǟ" ǥǻşÀɀɉ ǼĿǄɀǫÊǺ

øǺǤǫǹɍǟ" ȷǟɀǺȝ ǨƠ ȣɀòɀȠ ɀȽ ǺȴõǺ øǺǤǫǹɍǟ ĘǤÛǺ :**Bacterial endotoxins** ǤĿȠɀǫǺƨǟ ǤĿŶǹǟǼǚǟ ğǺǫǺǺØǚǟ
Ü(ǤǺÂĿŶȮǫɋǟ ǤǺÊǺǚǟ Ž 30 ǤȞǺÔǚǟ Û5 ǼŶǑǟ) "Test for Bacterial endotoxins ǤĿŶǹǟǼǚǟ ǤĿȠɀǫǺƨǟ ğǺǫǺǺØǚǟ ȬǅZɉ
.ÿǟǺɋ ȜŶĿʈǟ Ž ǤĿǚşǻ ǥǼǥş 0.03 RS ȜŶǹǟǼǚǟ ȷǺǺØǚǟ ȡȠ ʔɀǫɨǟ àşǺǅɀǫǺ ɾ

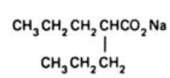
NATRII VALPROAS

Sodium valproate !ǋǰǡǋƬǁɛ ǀɛǋǶǤǁǷƺ

$C_8H_{15}NaO_2$:**Molecular formula** ǤĿǺǺÂƨǟ ǤȣĿÔǚǟ

166.2 :**Relative molecular mass** ǤĿǤÊǺǚǟ ǤĿǺǺÂƨǟ ǤŶǫȮǚǟ

:**Graphic formula** ǤĿǫǺĿǤʈǟ ǤȣĿÔǚǟ



:**Chemical name** ȜəǺĿȴĿȮǚǟ ȴèɾǟ

Sodium 2-propylvalerate; sodium 2-propylpentanoate; CAS Reg. No. 1069-66-5.

.ǺǤǺÀǬǨ ǤȞǟǟÀǚǟ ǅǼȝ şǕ ǤȞǟǟÀǚǟ ǅǼȝ ÜǺǤǺÀǬǨ ȐĿǟǕ şǕ ÛȐĿǟǕ ȸøɀŶǟ ȧɀȞÊȠ :**Description** Ȥòɀǚǟ

.TS (ȯ/ȟ750~) ȯɀǫǺǯǺǫǟş ǒǺʈǟ Ž ȷǺǟşØǚǟ ǺǤǥ :**Solubility** ǤĿǫǺǟşØǚǟ

.ţÀÔǚǟ ǻǺȒȠ ǚǟşǻ :**Category** ǤǺǺǚǟ

.ǺǼǻDZ ĞǑŶ8ƞ ǴǺşǺǵ Ž ȳʐǺáʐÔǖǟ ğǟşƎǑǺʐ ŞǺǵ Ǣʑ :**Storage** ȸǺÂǺÅǬǖǟ

.Ǵ3ʐǺƞ ȳʐǺáʐÔǖǟ ğǟşƎǑǺʐ :**Additional information** ǴǺʐǺȑǕ ğǺƞʐŶȞƞ

REQUIREMENTS ƘǴǓǓƱǩǳ!ƒ

ȸ3 ǼǺÂǺ ɍş %98.0 ȸ3 ǑǑǺ ɍǺƞ ʔŶ3 ȳʐǺáʐÔǖǟ ğǟşƎǑǺʐ Ƀʐ0Ơ :**General requirement** ȳǺȞǖǟ ǼŶÛǬƫǟ

.ǴǺǺǑǟ ǥǺƫǟ ƂǕ ƫʐDZǺǑǺǟ Ǵǟʐ ÊȚ Û$C_8H_{15}NaO_2$ ȸƞ %101.0

:**Identification tests** ƕǏǸǊǈǈ Ɩ ƐƥƑǴȾƐ

(ȯ/ȟ70~) Ǽǻǿʐ Ŷ ȭşǿǼƮǟ Ȑ Ƥ ȸƞ Ǒƞ 1ş R ȳǿʐʐşǿʐŶȮǖǟ ȸƞ Ǒƞ 5 ȣǺȒǺ ÛǒǺƞ Ǒƞ 5 Ž ȟ0.5 ǟǟǾǺ :A

ǺǺǴǺş ÛǴǺǺ ÛR ǴƎǺƞŸǖǟ ȳʐǺáʐÔǖǟ ğǺǺŶÊǟ ʔŶǺÊǖǟ ǴǑǴÛǖǟ ǷǺΘ ÛǑÔǺǺǖ ȭǺǬǺ ÛǥǼǵǟş ǴǑǥǟá ǥǼƞ ǥʐǑǟ ǯǺƚ ÛTS

ǴǑÛǺƞ Ž Ʉǟʐ ȒǖǟǷǺÛǖǟ ǟǺǥ" ǰǟʐǺ3 ǨƠ ȣʐȍʐƞ ʐȽ ǺȶȭǴǺȶǮǖ ƐǺǥǺǖǟ ȽǺǖǟ ǿǺǴǬǹǟ ʔǺʑ .ȣǺǺƨǟ ʔǿǬǵ

ȋǺÔǬƞǟ ǷǺù ƐǟǺÛǬǺ .(43 ǴȞǺÔǖǟ Û1 ǼŶǑǟ) "Spectrophotometry in the infrared region ǒǟǺȶΣǟ ǨƠ ǴȞȉ ɉǟ

.ȬǺşƎǑǺǺǖǟ ȐȶΣ ɄȞDZǺƫǟ ǷǺÛǖǟ 3ƞ şǕ RS ȬǺşƎǑǺǺǖǟ Ȑ Ƥ ȸƞ ȼǼŶ3 ǑÔɄǬÊƫǟ ǷǺÛǖǟ 3ƞ ǒǟǺȶΣǟ ǨƠ ǴȞȉ ɉǟ

ÛǴǺǬǟʐDZǿǕ ǴǟǺèǿ ǰǬǺǺ ÛTS (ȯ/ȟ 100) (II) ǨǒǺǟʐȮǖǟ ğǟǺǬǬ ȸƞ Ǒƞ 1 ȣǺȒǺş ǒǺƞ Ǒƞ 5 Ž ȟ0.5 ǟǟǾǺ :B

.R ǰʐǟǺȮǖǟ ǼǺǿʐŶȭ Ʉ3ǺǟǿŽ ǴǟǟşǢ ǰʐȮǩ

General ǴƞǺȞǖǟ ȣǟǺȞǬèɍǟ ğǟǿǺǴǬǹǟ" ǰǟʐǺ3 ǨƠ ȣʐȍʐƫǟ ÛB Ǒ3ǺǺǬǖǟ Ǒƞ/ȠŶƞ 20 ȯʐŶȚ ɄÛȞǺ :C

.(125 ǴȞǺÔǖǟ Û1 ǼŶǑǟ) ğǺǺŶÊŶǖ ǺƮȶȭ "identification tests

ǿǺǴǬǹɍǟ " ǰǟʐǺ3 ǨƠ ȣʐȍʐƞ ʐȽ ǺȶȭǿǺǴǬǹɍǟ ȯʐŶȚ ƘȒɄǬǖ ȟ1.0 ȳǼǺǬÊǺ :**Heavy metals** ǴŶƮǑǯǖǟ ǰǺǺȞƫǟ

ǰǺǺȞƫǟ ʔʐǬȚ ƙȞǺ Ü(127 ǴȞǺÔǖǟ Û1 ǼŶǑǟ) 3 ǒǟǺDZqǟ "Limit test for heavy metals ǴŶƮǑǯǖǟ ǰǺǺȞƫ ǑDZɉ ɃǂΣǟ

.ȟ/ȳǟǺȡşǺǑƞ20 ȸ3 ǼǺÂǺ ɍ Ü(128 ǴȞǺÔǖǟ Û1 ǼŶǑǟ) A ǴǑǺǺÛŶǖ ǺǑǴù ǴŶƮǑǯǖǟ

ǿǺǴǬǹɍǟ" ǰǟʐǺ3 ǨƠ ȣʐȍʐƞ ʐȽ ǺȶȭǑ 3ǟǺǬǺş ÛǒǺƫǟ ȸƞ Ǒƞ 35 Ž ȟ5.0 ȯʐŶȚ ȳǼǺǬÊǺ :**Arsenic** ǸƮǬǿÂǖǟ

.ȟ/ȳǟǺȡşǺǑƞ 2 ȸ3 ǸƮǬǿÂǖǟ ʔʐǬȚ ǼǺÂǺ ɍ Ü(130 ǴȞǺÔǖǟ Û1 ǼŶǑǟ) "Limit test for arcinic ǸƮǬǿÂǖǟ ǑDZɉ ɃǂΣǟ

ȸƞ Ǒƞ 20ş TS (ȯ/ȟ130~) ȬǺǺǬǺǖǟ Ȑ Ƥ ȸƞ Ǒƞ 2 ȸƞ ǰǺǺƞ Ž ȟ1.20 ǟǟǾǺ :**Chlorides** ğǟǼǺǿʐŶȮǖǟ

Û1 ǼŶǑǟ) "Limit test for chlorides ğǟǼǺǿʐŶȮǖǟ ǑDZɉ ɃǂΣǟ ǿǺǴǬǹɍǟ" ǰǟʐǺ3 ǨƠ ȣʐȍʐƞ ʐȽ ǺȶȭǑ 3ǟǺǬǺş ÛǒǺƫǟ

.ȟ/ȠŶƞ 0.2 ȸ3 ǼǺǿʐŶȮǖǟ ʔʐǬȚ ǼǺÂǺ ɍ Ü(124 ǴȞǺÔǖǟ

ǿǺǴǬǹɍǟ" ǰǟʐǺ3 ǨƠ ȣʐȍʐƞ ʐȽ ǺȶȭǑ 3ǟǺǬǺş ǒǺƞ Ǒƞ 40 Ž ȯʐŶȚ ƘȒɄǬǖ ȟ0.2 ȳǼǺǬÊǺ :**Iron** ǼǺǼΣǟ

.ȟ/ȳǟǺȡşǺȮƞ 50 ȸ3 ǼǺÂǺ ɍ Ü(129 ǴȞǺÔǖǟ Û1 ǼŶǑǟ) "Limit test for iron ǼǺǼΣ ǑDZɉ ɃǂΣǟ

ɃÆΣ ǿȦǬǹɍ" ȷǟȤȦ3 ǨƠ ȣȤòȤƞ ȤĿ ȦȶÕ 3ǟȦǬȿ ǒȦʈ ȸƞ Ōƞ 20 Ž ȟ2.5 ǡǟØȦ :**Sulfates** ğȦȦŸÊǒǟ
.ȟ/ƞŸƞ 0.2 ȸ3 ğȦȦŸÊǒǟ ȜȤǬȚ ÆȦÂȦ ɍ Ü(125 ǦȞȦÔǒǟ Û1 ÆŸŎǟ) "Limit test for sulfates ğȦȦŸÊǒǟ ŌDZɉ

ǒȦʈ ȸƞ Ōƞ 10 Ž ȟ 2.0 ȯȤŸȚ ӯȤȶȡ ȷȤȮȦ ɍ :**Clarity and colour of solution** ȯȤŸǂǟ ȷȤǒȿ ǒȦȦÔǒǟ
.¢ǒ ȷȤǒ ɍ ȯȤŸǂǟȿ TS2 ɃǿȦÆȞʈ ӯȤȶȡ ȸƞ ǥÆȉ ȦǯõǕ R ȷȤǟȦȮǒǟ ÆÆÊõǕ ȺǝȦȦǬ ȸƞ ƃȦȴǟ

ȸƞ ȦǯõǕ ÆŐȦǒǟ ȷȤȮȦ ɍ Û°ӯ105 ǥǿǟȦǵ ǦDZǿǻ ÆȦ3 ǨǟȦǬ ȷǟȿ ȝøǬǵ ȤȦƨ :**Loss on drying** ȤÆȦDZǬǒȦǟ ÆŐȦǒǟ
.ȟ/ƞŸƞ 20

ȷȤǟȦȮǒǟ ÆÆÊõǕ ȺǝȦȦǬ ȸƞ ƃȦȴǟ ǒȦʈ ȸƞ Ōƞ 20 Ž ȟ2.0 ǡǟØȦ :**Acidity or alkalinity** ǦȦȤŸȰǒǟ ȿǕ ǦȓȤȶΣǟ
0.1) ӯȤȦǻȤÔǒǟ ÆÆÊõȿǿÆȽ ȸƞ Ōƞ 1.5 ȸƞ ȦǯõǕ ÆŸÛǬȦ ɍ ÜTS ȯȤȹǯǕ/ƙȦǒǯȤ ȯȤÆȤ ȸƞ Ōƞ 0.1 ȣȦȒȦȿ R
ȦȞÎȶŸǒ ȝÛèȤǒǟ ǦÛŐȦǒǟ ȝŸ3 ȯȤÔȞŸǒ VS (ȯ/ȯȤƞ 0.1) ŐȦǿȤŸõȿǿÆȽǟ Ȓƥ ȸƞ Ōƞ 1.5 ȿǕ VS (ȯ/ȯȤƞ
.(ȺŸȦȹȦȩ)

Gas ǟȦȣǒǟ ǡǟȦÎǬèǟ" ȷǟȤȦ3 ǨƠ ȣȤòȤƞ ȤĿ ȦȶÕ ǿȦǬǹɍǟ ɃȦƨ :**Related substances** ǦǒȦÎʈ ǻǟȤʈ
:ŐÆǒȦȚ 3 ӯǟÆȦǬèȦǟ (101 ǦȞȦÔǒǟ Û1ÆŸŎǟ) "chromatography

Ōƞ 1 Őõ Ž (internal standard ȺŸǹǟǻ ǿȦÆȞƞ) octanoic acid R ŐȦȤȹȦǬõȿɉǟ ȒƥƤ ȸƞ 3ƞ 0.20 *:1 ȯȤŸǂǟ*
.(dichloromethane) R ȷȦǯÆƞȿǿȤŸõ ȺǝȦȦǬ ȸƞ

ǆȦȿ ÛTS (ȯ/ȟ190~) ŐȦǿȤȦŸÊǒǟ ȒȶШ Ȓȶ3 ÛǒȦƞ Ōƞ 10 Ž ǦòȤȞȦʈ ǥǻȦʈ ȸƞ ȟ 0.50 ǡǟØȦ *:2 ȯȤŸǂǟ*
combined ǦȞȶŎǟ ȷȦǯʈ ǿȤŸõ ȺǝȦȦǬ ğȦòŸǹ ŐÊȣǩ .Ōƞ 20 ǥÆǵǟȿ Őõ R ȷȦǯÆƞȿǿȤŸõ ȺǝȦȦǬ ȸƞ ğȦÆȶõ 3 3ƞ
°ӯ30 ǟȿȦDZǬǩ ɍ ǥǿǟȦǵ ǦDZǿǻ ÆȦ3 ǦǥȦȉȦǒǟ ȦȦǦǩȿ ǴȉȦǩ ÛR ǦÆǝȦƞŸǒǟ ӯȤȦǻȤÔǒǟ ğȦȦŸè 3ƞ ǆȦȴ ÛǒȦʈ ȸƞ Ōƞ 10 3ƞ
.ǿǟȿǻ ȦȦǤƞ ӯÆȦǬÊȦ ÛǨǤȦȦŐǩ Ōƞ 10 ƞŸǤȦ ȴDZǵ ȝøǬǵ

10 Ž R ŐÆȤȹȦǬõȿɉǟ ȒƥƤ ȸƞ ƞŸƞ 2.0 ȸƞ ǰȦÂƞ Ž Ōƞ 10 Ž ǦòȤȞȦʈ ǥǻȦʈ ȸƞ ȟ0.50 ǡǟØȦ *:3 ȯȤŸǂǟ*
3 3ƞ ǆȦȿ ÛTS (ȯ/ȟ190~) ŐȦǿȤȦŸÊǒǟ ȒȶШ Ȓȶ3 ÛVS (ȯ/ȯȤƞ 0.1) ӯȤȦǻȤÔǒǟ ÆÆÊõȿǿÆȽ ȸƞ Ōƞ
10 3ƞ combined ǦȞȶŎǟ ȷȦǯÆƞȿǿȤŸõ ȺǝȦȦǬ ğȦòŸǹ ŐÊȣǩ .Ōƞ 20 ǥÆǵǟȿ Őõ R ȷȦǯÆƞȿǿȤŸõ ȺǝȦȦǬ ȸƞ ğȦÆȶõ
ȝøǬǵ °ӯ30 ǟȿȦDZǬǩ ɍ ǥǿǟȦǵ ǦDZǿǻ ÆȦ3 ǦǥȦȉȦǒǟ ȦȦǦǩȿ ǴȉȦǩ ÛR ǦÆǝȦƞŸǒǟ ӯȤȦǻȤÔǒǟ ğȦȦŸè 3ƞ ǆȦȴ ÛǒȦʈ ȸƞ Ōƞ
.ǿǟȿǻ ȦȦǤƞ ӯÆȦǬÊȦ ÛǨǤȦȦŐǩ Ōƞ 10 ƞŸǤȦ ȴDZǵ

ȦǬȖ ÆõȦƞ ȸƞ ǦÆȤȦõ ǦÆȶȮǟ Ǭǭ ÛȴèȤ 0.4 ȺŸǹǟÆǒǟ ǬȦÛȩȿ ӯ 1.5 ȯȤÛǟ ȺDZȦDZǟ ǻȤȶ3 ӯÆȦǬÊȦ ǒǟȦDZǭǟ ŌDZǕ ȸƞ
ŐȦǿȤȦèȤȦǒǟ ȒƥƤ ȸƞ ȟ1 3ƞ ǦȤè ÛŐÆǒȦǯȦȦȦǬǒǟ ȒƥƤȿ M 20 ȯȤȡȿȦõȦƞ ȦǬèǟ ȸƞ ȷȤȮƞ ǿȤÛǒ ȟ15
silanized R ŐÆȹŸÆÊǒȦǟ ŌƞȦȞƞ ɃǿȤÛÎƞ ӯȦ3ǻ ÛȯȤÊȣƞ ȒƥƤ ȸƞ ȟ84 øǟ ǦȶȢÆƞ TS (ȯ/ȟ1440~)
R ƙDZȿȦǬȦǒǟ ӯǟÆȦǬèȦǟ Û°ӯ170 ǥǿǟȦǵ ǦDZǿǿÆǟ ǻȤȶȞǒǟ ȝŸ3 ȘȤȦ3 .(ȦǬƞȿȦȮƞ180-150) diatomaceous support

[illegible]

Assay: [illegible] 0.25 [illegible] 30 [illegible] R1 [illegible] 0.15 [illegible] -1 [illegible] TS [illegible] (0.1 [illegible]) VS [illegible] A [illegible] "Non-aqueous titration" [illegible] 142) [illegible] 1 [illegible] (0.1 [illegible]) VS [illegible] 16.62 [illegible] $C_8H_{15}NaO_2$.

NEOMYCINI SULFAS

Neomycin sulfate [illegible]

Composition: [illegible] *Streptomyces fradiae* [illegible] B [illegible] C.

Chemical name: [illegible]

Neomycin sulfate; CAS Reg. No. 1405-10-3.

Description: [illegible]

Solubility: [illegible] (~750 [illegible]) TS [illegible] R [illegible] R [illegible] R.

Category: [illegible]

Storage: [illegible] 30° [illegible]

Additional information: [illegible]

REQUIREMENTS [illegible]

General requirement: [illegible] 600 [illegible]

.[illegible]

:**Identification tests** [illegible]

"Thin-layer chromatography [illegible] :A [illegible] TS (ȯ/ȟ40) [illegible] R3 [illegible] (84 [illegible] 1 [illegible]) [illegible] 20 (A) [illegible] (1) [illegible] 20 (B) [illegible] RS B [illegible] 105° [illegible] 10 [illegible] 5 [illegible] 105° [illegible] .TS [illegible] .B [illegible] A [illegible]

:B [illegible] 10 [illegible] 5 [illegible] 0.1 [illegible] R 2 [illegible] TS (ȯ/ȟ1) [illegible] 65 [illegible] 70° [illegible] 10 [illegible]

General [illegible] "identification tests [illegible] A [illegible] 0.05 [illegible] :C .(123 [illegible] 1 [illegible])

.ȟ/[illegible] 10 [illegible] :**Sulfated ash** [illegible]

[illegible] 0.6 [illegible] 60° [illegible] :**Loss on drying** [illegible] phosphorus pentoxide R [illegible] 5 [illegible] 3 [illegible] .ȟ/[illegible] 80 [illegible]

.7.5-5.0 [illegible] R [illegible] 0.10 [illegible] :**ph value** [illegible]

Thin-layer [illegible] :**Neamine** [illegible] "chromatography [illegible] (84 [illegible] 1 [illegible]) [illegible] 0.3 [illegible] R [illegible] 240 [illegible] 7 [illegible] .R3 [illegible] 30 [illegible] TS (ȯ/ȟ80~) [illegible] 0.75 [illegible] 110° [illegible] .TS (ȯ/ȟ100) [illegible] 10 [illegible] 2.5 (A) [illegible] 0.05 (B) [illegible] RS [illegible]

Ž ăäÀÎǪèꞅă ÙÛÛƯ ÒꞪÀʌ .ǦÕǮęấ 15 gǽꞑ °ÿ110 gøäÀǵ ǦDZøấ ǼÀȝ ȸǺÊǩꞩ ÛTS ɃÀʌǼÔṎä ǼÀøζŸõ/ȸʌǼÀʌøǼǮȽ ÀȚǮŸȝ ÕÔꞪǪÊʈä ȭŸǩ ȸȝ gǽÌ ÀǯṏÛ ȷζÒǩ ꞅ ƙꞑÀǼÀöä ĘæÀÛǩ A ȯζŸꝥÀæ ÀȚǮŸȝ ÕÔꞪǪÊʌ ǦȞÕæ ɃÛ .øÀȚÀöä ŏζȑ .B ȯζŸꝥÀæ

ȭʌøζŸõşøǼǮȚä Ȑ ƥ ȸꞑ Õꞑ 3 ȣÀȒʌş ŏÀꞑ Õꞑ 200 Ž ȟ1 ăäØʌ :**Content of sulfates** ğÀÀŸÊöä ȝζǪƮ Ž ȸǺÊʌ .TS (ȯ/ȟ50) ȸǹÀÊöä ÿζʌøÀǤöä ǼʌøζŸõ ȸꞑ Õꞑ 25 ȣÀȒʌş ÛȷÀǮŸȣöä ꝛøǪǵ ȸǺÊʌ ÛTS (ȯ/ȟ420~) ǜζÀÒʌ ǦöÀȽǯöä Ž ÿäÀȡ Ṏõ .ȷäζǩş ÛǼꞑÀǩ ÛƵÀΘ ÛöÀʈÀæ ÕÊȣǩ ÛǦæÀèÀöä ȝȽΘ ÛȭʌÀꞪǪöä ȝꞑ ğÀȝÀè 4 gǽꞑ ꞪəÀꞑ ÿÀƥ .ȟ/ꞑŸꞑ 310 ȸȝ ǼʌÂʌ ꞅş ȟ/ꞑŸꞑ 250 ȸȝ ğÀÀŸÊöä ȝζǪƮ ṎÕʌ ꞅ Üğ ÀÀŸÊöä ȸꞑ ꞑŸꞑ 411.6

ǦʌζǮΣä ğäấÀȒȽŸö ǦǮDZζỏζǮǤöä ǦÊʌÀṎʈä" ȷäζÀȝ ǨƠ ȣζòζꞑ ζȽ ÀȽõ ǦÊʌÀṎʈä ĘǤÛǩ :**Assay** ǦÊʌÀṎʈä NCTC) *Bacillus pumilus* (*a*) Àꞑ̈Û ÿǼǺǪÊʌ Û(155 ǦꞪÀÔöä Û1 ǼŸṎä) "Microbiological assay of antibiotics ŏÀȽÀæ ÛǦȽǮṎȝ ğÀÀèζζ Ǧəøäấ Û8.1-8.0 ꞪəÀǼ ŏÀȽÀæ ȝꞑ Cm1 ʈøà Ùèş ÛøÀǤǪǹä ÿζǪÀDZṏ (8241; ATCC 14884 gøäÀǵ ǦDZøấş Û(ÀǪö ꞪŸǮʈä Ṏõ Ž Ǧǯöşấ gǽǵş 14ş 2 ƙæ gấÀȝ) ƙÊʌÀꞑζǮÀöä ȸꞑ ǼèÀʌꞑ ÂǮõÀǩ ÛTS2 şÛ TS1 Û8.0 ÛøÀǤǪǹä ÿζǪÀDZṏ (ATCC 29737) *Staphylococcus aureus* ǦǮȽØöä ǦʌấζṎÀȞöä ğäøζȮʈä (*b*) şÛ Ü°ÿ39-35 ǦǪÀȒǵ ȸꞑ ǼèÀʌꞑ ÂǮõÀǩş ÛTS2 şÛ TS1 Û8.0 ŏÀȽÀæ ÛǦȽǮṎȝ ğÀÀèζζ Ǧəøäấ Û8.0-7.8 ꞪəÀǼ ŏÀȽÀæ ȝꞑ Cm1 ʈøà Ùèş ǦʌấζṎÀȞöä ğäøζȮʈä (*C*) şÛ Ü°ÿ39-35 ǦǪÀȒǵ gøäÀǵ ǦDZøấş Û(Õꞑ1 Ṏõ Ž Ǧǯöşấ gǽǵş20ş 2 ƙæ gấÀȝ) ƙÊʌÀꞑζǮÀöä 8.1- ꞪəÀǼ ŏÀȽÀæ ȝꞑ Cm1 ʈøà Ùèş ÛøÀǤǪǹä ÿζǪÀDZṏ (ATCC 12228) *Staphylococcus epidermidis* ǦʌşÀÎǤöä Ǧǯöşấ gǽǵş2ş 0.5 ƙæ gấÀȝ) ƙÊʌÀꞑζǮÀöä ȸꞑ ǼèÀʌꞑ ÂǮõÀǩş ÛTS2 şÛ TS1 Û8.0 ŏÀȽÀæ ÛǦȽǮṎȝ ğÀÀèζζ Ǧəøäấ Û8.0 ǦǮöÀȞÀöä Ž ǖÛƖ gǽȽǪȞʈä ấşǼΣä Ž ǦÊʌÀṎʈä Ǧęấ ȭ̈Ṏǩ ꞅ .°ÿ39-35 ǦǪÀȒǵ gøäÀǵ ǦDZøấş (Õꞑ 1 Ṏõ Ž ǦǮöÀȞÀöä ȸꞑ %105 ȸȝ ǼʌÂǩ ꞅş %95 ȸȝ (*P* = 0.95) fiducial limits of error of the estimated potency gøǮṎʈä ꞪŸǮʈä Ž ƙÊʌÀꞑζǮÀöä ȸꞑ Ǧǯöşấ gǽǵş 600 ȸȝ ṎÕʌ ꞅ (*P* = 0.95) gøǮṎʈä ǦǮöÀȞÀöä ǖÛǹ ǼȽǪȞʈä ɃζŸȞöä ǼΣä .gøǮṎʈä .ǦÀÀÕä gấÀʈä ƂÛ ʈζDZÀöÀæ ǦæζÊƮ ÛÿäÀȡ

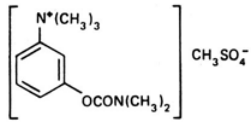
NEOSTIGMINI METILSULFAS

Neostigmine metilsulfate DZĩDZǮƸꝥꞩ ǋĩǳǁ ǀƑ2ꝥꞩ ǖĩƗĩDZ

$C_{13}H_{22}N_2O_6S$:**Molecular formula** ǦǮÀʌÂꞩä ǦȣǮÔöä

334.4 :**Relative molecular mass** ǦǤÊÀöä ǦǮÀʌÂꞩä ǦŸǪȮöä

:**Graphic formula** ǦǮǪÀǮǤʈä ǦȣǮÔöä



:**Chemical name** ȹəǺƪŧƪȮöä ǈèғǟ

(*m*-Hydroxyphenyl)trimethylammonium methyl sulfate dimethylcarbamate; 3-[[(dimethylamino)carbonyl]oxy]-*N*,*N*,*N*-trimethylbenzenaminium methyl sulfate; CAS Reg. No. 51-60-5.

.ǴĦəäÀöä ƇǼƺ ÛȒƪǣǚ Ƀǿ ȥǞǣ ȧȥĦÊɳ :**Description** Ȥòȥöä

.TS (ȯ/ȟ750~) ȯȥǿǰƪqǟ Ž ȷǢşǾöä Ǻǵ ÜŏǺţǟ Ž ǺǼǱ ǡǟşǽ :**Solubility** ǴǿǢşǾöä

.ŌǶǺöä ƗƪöȥǬ :**Category** ǴǺǺöä

.ŏȥȒöä ȡɳ ƾŧƠ ȷǛş ÛȳǺȮǵǖǣ ǴŌǛ8ɳ ǴǺşǺǵ Ž ƙŧ8ǪèȥƪǺöä ğǺǺǛè ŌƪǪƪɳ ȘǺǵ Ǽƶ :**Storage**ąȡǺÂǺǪöä

REQUIREMENTS ƘǴǛƱƙǳ!ƒ

ǼǺÂǺ ғş %98.0 ȡƺ ŌŌǺ ғ Ǻɳ ƾǛƺ ƙŧ8ǪèȥƪǺöä ğǺǺǛè ŌƪǪƪɳ ɃȥǪƠ :**General requirement** ȳǺǶöä ǼǛÛǪţǟ

.ǴǺǺŎä ǥǻǺţǟ ƂǛ ţȥǱǺöǺǣ ǴǣȥÊȚ $C_{13}H_{22}N_2O_6S$ ȡɳ %100.5 ȡƺ

:**Identification tests** ƕǏǸǊǇǁ ǀ ǫƥƑǂǬǁ

.DȘ CȘ B ğǟǿǺǪǹғǟ şǛ DȘ A ȷǟǿǺǪǹғǟ ĘǴÛǺ ȷǛ ȡȮȥ •

ŏǟǺŧΣǟ ƘƠ ǴȞìȷǟ ǴŌÛǺɳ Ž ȹəȥȒöä ȤƪÛöä ǡǺǢĝ" ȷǟȥǺƺ ƘƠ 8ȥòȥɳ ȥȽ Ǻŧő ǿǺǪǹғǟ ĘǴÛǺ :A ŏǟǺŧΣǟ ƘƠ ǴȞìȷǟ îǺÔǪɳǟ Ȥƪù ĘǢǺÛǪ .(43 ǴĦǺÔöä Û1 ǼǛŎä) "Spectrophotometry in the infrared region

.ƙŧ8ǪèȥƪǺöä ğǺǺǛè ŌƪǪţ ȹǶǱǺţǟ ȤƪÛöä ƺɳ şǛ RS ƙŧ8ǪèȥƪǺöä ğǺǺǛè ŌƪǪɳ ȡɳ ȼǛƺ ŌÔĦǪÊţǟ ȤƪÛöä ƺɳ

ǺǲǛƺ ŌÔĦǪÊţǟ ǴǶŌǴöä ĘǢǺÛǪǩ ."Related substances ǴŏǺÎţǟ ǻǟȥţǟ" ȷǟȥǺƺ ƘƠ 8ȥòȥţǟ ǿǺǪǹғǟ ǺŢǫǟ :B

.C ȯȥǛƚǺǣ ǺǲǛƺ ŌÔĦǪÊţǟ ŌǛǩ ƺɳ ǴȥǺǰȮöäş ǺǲȚţǟş ȷǺȮţǟ Ž B ȯȥǛƚǺǣ

ȹəǺɳ ȳǺƥ Ž TS (ȯ/ȟ750~) ȯȥǿǰƪqǟ ȡɳ Ōɳ 2Ș R ȳȥƪèǺǩȥǴöä ǼǛÊŏşǿǼǱ ȡɳ ȟ0.4 ƺɳ ȟ0.05 ȡǺÊǺ :C

ȒƥȡɳŌɳ 2Ș ŏǺɳ Ōɳ 2 8ǺȒǺş ÛǻƎǺ ÛTS (ȯ/ȟ750~) ȯȥǿǰƪqǺǣ ȹǛòȷǟ ǈǱΣǟ ƂǛ ǴĦÔƚ .ĘəǺǥǻ 3 ǥǼɳ

.ǺƥǛ ȷȥö ǰǪǺ ÛTS ŌǼȥǺǛè ȹəǺǪ ȡǺøǺǣşäǺǼöä

ǴǛǪȮöä ƾǛ8ǩ ÜǥƘ8ò ǴŌǩȥǣ Ž ǿǺǲÔǪғǟ ƾøǪǵ ȡǺÊǺş R ȳȥǺǻȥÔöä ğǺǪȥǣǺȭ ȡɳ ȟ0.5 ƺɳ ȠǛɳ 20 ǯǺȥ :D

ƾøǪǵ ȡǺÊǩ ÜǴǵǺìǺöä ƂǛ ÛTS ƙɳşƎöä ȡɳ Ōɳ 0.2 8ǺȒǺ .ǴìǺǩ Ż ÛƘǪǺǪǩ ƾøǪǵ ŏǺɳ Ōɳ 10 ƺɳ ǥǺǲÔǺţǟ

A ŌƺǺǺǪöä ǰǩǺǺöä ȯȥǛƚǟ ȹÛǶǺ ÜȷǺǼǛ8ǺǢ ƙɳşƎöä ǼǺǻ ǻǺÛǺş ÛTS (ȯ/ȟ70~) ŌǺǿȥǛȭşǿǼǱǟ ȒŧǕ ȒƫƠ ÛȷǺǼǛ8öä

Û1 ÆŸÕā) ğÅŸÊŸ ÅŁŧŧõ "General identification testes ǦŋÅȞā 8āÀȞèŗā ğāøÅǪǹā" Jāζ3 ĶƠ 8ζòζţā .(123 ǦĦÀÔā

.ğÅ3Åè 3 gÆŋ °ÿ105 gøāÀǵ ǦDZøÆ ζŁÅDzǪā ÆȞ °ÿ149-144 :**Melting range** øÅȚÔφŗā ȯÅf

1ş TS (ȯ/ȟ130~) ŎÅǪÅā Ȑþ ȡŋ Ōŋ 1 8ÅȒş ÛòÅŋ Ōŋ 10 Ž ȟ0.20 āāØ :**Chlorides** ğāÆøζŸȮā .gÀìÅǤŋ ÿζŧȡ ÀȚŢŋ ŞǵŸ ŗ .TS (ȯ/ȟ40) ǦȒÀā ğāÀǪ ȡŋ Ōŋ

TS (ȯ/ȟ70~) ŎøζŸõşøÆŁTā Ȑþ ȡŋ Ōŋ 1.5 8ÅȒş ÛòÅŋ Ōŋ 10 Ž ȟ0.20 āāØ :**Sulfates** ğÅŸÊā .ÂŁÅDZ ÀȮ3 ÀȚŢŋ ǰǪ ŗ .TS (ȯ/ȟ50) ÿζøÅǤā ÆøζŸõ ȡŋ Ōŋ 1ş

ŗş 8Åò òÅţā ȡŋ Ōŋ 10 Ž ȟ0.20 ȯζŸŢ JζȮ :**Clarity and colour of solution** ȯζŸŧā Jζȯş òÅÅò ŌāζÊā Jζȯ" Jāζ3 ĶƠ 8ζòζŋ ζŁ Åŧõ JøÅŌ ÅŋÆ3 Bn1 ɃøÅȞţā ȯζŸŧā Jζȯ ȡ3 JǭŸǪā Ž gÆì ÀǰõÛ JζȮ .(53 ǦĦÀÔā Û1 ÆŸÕā) "Colour of liquids

.ȟ/ŋŸŋ 1.0 ȡ3 ÆÂ ŗ :**Sufated ash** ĶŸÅÊţā ǻŋÀā

ȡŋ ÀǰõÛ ÆŌÅā JζȮ ŗ Û°ÿ105 gøāÀǵ ǦDZøǻ Æ3 ĶÅǭ Jàş ʔøǪǵ ζÅʑ :**Loss on drying** ζŁÅDzǪÅ ÆŌÅā .ȟ/ŋŸŋ 10

JζȮ ÜTS ȯζφÅǰÛ/ƙÅòÅǰζ ȯζÆζ ȡŋ Ōŋ 0.1 8ÅȒş òÅţā ȡŋ Ōŋ 10 Ž ȟ0.20 āāØ :**Acidity** ǦȑζŧƩā .ÀþÛ ȯζŸŧā ǴǤÔ ÜVS (ȯ/ȯζŋ 0.01) ÿζǻζÔā ÆŁÊõşøÆŁ ȡŋ Ōŋ 0.30 8ÅȒ .JζŸā ƇÆ3 øÅǤǹŗā ȯζŸŢ

ǦŌŁęÀā ǦǤÛā āāÀÎǪèā" Jāζ3 ĶƠ 8ζòζŋ ζŁ Åŧõ øÅǤǹŗā ĘǤÛ :**Related substances** ǦòÅÎţā ǻāζţā 67 ȡŋ ǰÂŋş ǦŸ8ŋ gǻŧõ R1 ÅȮŁŸÊā ǦŋŸŁ ÿÆǺǪÊ Û(84 ǦĦÀÔā Û1 ÆŸÕā) "Thin layer chromatography ǦĦŁÀÔā ȡŋ ǻÆŢ Ùy) õÀĦǪŋ øζÛõ R ƙŋŸŁǰÛ ɄāÅǭ ȡŋ ÿζDzǵ 3ş R ȯζφÅǰţā ȡŋ ÅŧDzǵ 30ş òÅţā ȡŋ ÅŧDzǵ ŌŁòÅŢ ȡŋ ÀǪşÀȮŋ 10 ǦĦŁÀò ʔŸ3 ŸÔÅŋ ĘǤÛ .(õÀĦǪţā øζÛā āØŁ 3ŋ ÅǤèÅŋ JζȮ ŗ JÛ ȡȮζ ŸǤę ǦŸ8ţā 3ŋ 0.10 (C)ş ÀǪ ɄŸŁţā Ž øÅǤǹŗā gǻŋ ȡŋ ŋŸŋ 0.10 (B)ş ÀǪ ɄŸŁţā Ž øÅǤǹŗā gǻŋ ȡŋ ŋŸŋ 20 (A) Ƀζʒ :ǦǪŸǪ ɄāζŁ øÅŁǩ Ž ζDzǪ õÀǪǩ āāÀÎǪèŗā gÀDzǵ ȡŋ ǦĦŁÀÔā ţÂφ ÆȞ .ÀǪ ɄŸŁţā Ž RS ƙŧ8ǪèζŁā ğÅŸè ŌŁǪŁŋ ȡŋ øÅŁǩ Ž ǦŁφÅǪ ǦĦŁÀÔā ζÅΘ .VS (ȯ/ȯζŋ 0.1) ÿζǻζÔā ÆŁÊõşøÆŁõ Ż ȡŋş TS2 ƙŸŁǪşÀǪ–4 ø ǽÀǩ Ûǜζāǻ ǦȞŌ ɃÛ JζȮǩ ŗ .øÅȚÅā òζȑ Ž āāÀÎǪèŗā ÙÛƯ ÒĦÀş ÛTS 2 ÿζŁèÅǩζǤā ğÅǩζŋÂşǻζŁ ǽÀǩ Ûǜζāǻ ɄāζŁ .B ȯζŸŧÅ ÅȚŁŸ3 ŌÔĦǪÊţā ŎŸǩ ȡ3 gÆì ÀǰõÛ ÛǦŁÊŁəÀā ǦȞŌǤā òÅǰǪèÅ ÛA ȯζŸŧÅ ÅȚŁŸ3 ŌÔĦǪÊ

ζÔφ ÅŁφζŋÛ ƘÛŌǩ àÅȚDZ ƂÛ ŌŌÅǩ ÛòÅŋ Ōŋ 20 Ž ÛǦŁùζǤȒŋ Ǧφşàζŋ Ûȟ0.15 ǦāÀę āāØ :**Assay** ǦÊÅŌţā

[illegible] .TS [illegible] (~400) [illegible] 25 [illegible] semi-micro [illegible]
[illegible] 200 [illegible] VS [illegible] 0.01) [illegible] 50 [illegible]
[illegible] TS [illegible] VS [illegible] 0.02) [illegible]
[illegible]
[illegible] 6.688 [illegible] VS [illegible] 0.01) [illegible] 1 [illegible]
.$C_{13}H_{22}N_2O_6S$

[illegible]

Additional Requirements for Neostigmini metilsulfate for parenteral use

.(56 [illegible] 4 [illegible]) "*Parenteral preparations* [illegible]" [illegible]

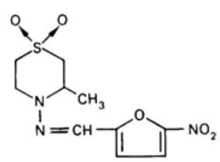
NIFURTIMOXUM

Nifurtimox [illegible]

$C_{10}H_{13}N_3O_5S$:**Molecular formula** [illegible]

287.3 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

3-Methyl-4-[(5-nitrofurfurylidene)amino]thiomorpholine 1,1-dioxide; 3-methyl-*N*-[(5-nitro-2-furanyl)methylene]-4-thiomorpholinamine 1,1-dioxide; CAS Reg. No. 23256-30-6.

[illegible] :**Description** [illegible]

[illegible] :**Solubility** [illegible]

[illegible] R [illegible] R [illegible]

.Antitrypanosomal drug [illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

ȡŋ %102.0 ȡʒ ÆÂÂ ɽʂ %98.0 ȡʒ ǬÕÂ ɽ Āŋ Èõʐȶƙøʐ ÀÆÂöä Ƀʐʒ :**General requirement** ÿÂĤöä ÆŸÛǪţä
.ĞÀÂÖä gấÅţä Ƃǚ ţʐDŽÀöÅǣ Ǧǣʐ ÊȚ Û$C_{10}H_{13}N_3O_5S$

:**Identification tests** ŀŭƝǈǁƐ lƐþƑǦǶƐ

- .ÅĤŋ CŞ B JäøÅǪǹɼä şǚ ȻÆģş A øÅǪǹɼä ĘǤÛÂ Jǚ Āŋǚ

:A ĘǤÛÂ øÅǪǹɼä Åȶõ ʐŁ ȢʐòʐŊ ǨƠ Jäʐȝ "ÂÆę ȁ ǮÛöä ƵʐʐȒRöä Ž ĞÕÛÅŋ ǦǨǰ ȷä ǦǨǰ ǨƠ ŏäÀȶΣä
"Spectrophotometry in the infrared region (43 ÆŸÖä Û1 ǦĤÂÔöä). ĘǣÂÛǪÂ ǮÛü ÅÔǪŋä î ǦǨǰ ȷä ǨƠ ŏäÀȶΣä
.Èõʐȶƙøʐ ÀÆÅŸö ȻĤDŽÀţä ǮÛöä ʒŋ şǚ RS Èõʐȶƙøʐ ÀÆÂöä ȡŋ ¢ŸÆʒ ǾÔĦǪÊţä ǮÛöä ʒŋ

:B ÀŢǾä øÅǪǹɼä ţʐòʐȢ ɼǵǬÅ ǨƠ Jäʐȝ "ţäʐấä ţäÎÅǦǒ "Related substances . ǩʐäʐĘ ǦÖǤöä ǦĤÀÆǦÊǦ
.C ǡʐŸǂÂǣ ÆŦŸʒ ǾÔĦǪÊţä ǾŸǩ ʒŋ ǵæÎöäş ÀŦȚţäş JÅÒţä Ž B ǡʐŸǂÂǣ ÆŦŸʒ ǾÔĦǪÊţä

:C ÂØä ā 20 ŋŸŋ Ž ĵÂÂŋ ȡŋ 2.0 Ǿŋ ÂÅÅǭʉ ŋÆŋŅŋøʐʐ ǾǦǯŋ R Æ 2.0ş Ǿŋ ȡŋ ǒÅţä .ÂȒÅ 8 0.25 Ǿŋ èŸÅǧ
R ÿøʐʐşøʐŸÒöä ȡŋ Ǿŋ 5 ÂȒÅ 8 .ȡõäấ ǹȒÀǚ Jʐö ĵǪÂ ÜR ȡÂÆÂƘǤöä ȡŋ ǧäÀÛę 4ş TS (ò/ȟ160) (II) ȁÅĦÂöä
.ǤǝÀţä ǤǾǤÛöä Ž ǹȒÀɟä JʐŸöä ʔǾǤǝʐ ÜʓÀƚş

.°ÿ182-178 :**Melting range** øÅŦÔǪɼä ǮÅƒ

.ȟ/ŋŸŋ 1.0 ȡʒ ÆÂÂ ɽ :**Sulfated ash** ǨÅŸÊţä ấÅŋÀöä

5.0 ȡʒ ÆÂÂ ɽ Ü°ÿ105 ǵøäÀģ ǦDŽøấ Æȝ ǨǣÅǪ Jäş ʔøǪģ ʐȤǮÀDzǪöÅǣ ÆǾÀöä :**Loss on drying**
.ȟ/ŋŸŋ

:**Related substances** ǦǒÅÎţä ấäʐţä ǦǾǤÛöä ǦǾǝęÀöä "ȁäÀÎǪèä Jäʐȝ ǨƠ ȢʐòʐŊ ʐŁ Åȶõ øÅǪǹɼä ĘǤÛÂ
"Thin layer chromatography (84 ǦĦÅÔöä Û1 ǦŸǑÖä) ÿÆÅǪÊǩ ǦŋŸŁ R6 ÅÒǝŸǝÊöä gấÅȶõ ǦŸǕ8ŋ (Æę ǦÒǩ Jʐ
øʐÛõ R JÅÊÒTäş R ǾǝʓÂqä ǧÅǪǝèǚ ȡŋ ǦÂşÅÊǪŋ ÿÅDzģǚ ȡŋ ĵÂÅŋş (ǦǤèÅÅŋ ǦÂøÅƟ øấÅÔŋ ȡŋ ŸǤę ǦŸŸ8ţä ǦĦǝÅÔöä
.õÀĦǪŋ ĘǤÛÂ ŸÔÅÅŋ ʔŸʒ ǦĦǝÅÔöä ǾǝöÅǂä ǦǪŸʓöä ǦǝöÅǪöä Ž Jʐǝèɟä R: (A) 10 ÀǪöşÀÒǝŋ ȡŋ Ƀʐǭ ʔŸʒ 10 ŋŸŋ
ÀǪöşÀÒǝŋ 2 (C)ş ÀǪö ȻŸǝţä Ž øÅǪǹɼä gấÅŋ ȡŋ ŋŸŋ1.0 ʔŸʒ JÅÂʐǪʒ ÀǪöşÀÒǝŋ 2 (B)ş ÀǪö ȻŸǝţä Ž øÅǪǹɼä gấÅŋ
JÅÂʐǪʒ ʔŸʒ ŋŸŋ 1.0 ȡŋ Èõʐȶƙøʐ ÀÆÂöä RS Ž ȻŸǝţä ÀǪö. ǩÀǪö õÀǪǩ ʒǾǤöä ǮDzǪö ǾǤę ş ʒȓ Ž ǦĦǝÅÔöä gÀDzģ
Ž ǮDzǪö õÀǪǩ ÛȁäÀÎǪèɼä gÀDzģ Ž ǦĦǝÅÔöä ʒʐø ÆĤǣ .ǈè 10 ǦʐÅÊŋ ǦĦǝÅÔöä ÀŦȚǩş ǦǨǤÎţä Ƙȡ ȁäÀÎǪèɼä
ÛA ǡʐŸǂä ȡʒ ǰǪǩ ǦǨǾǣ ǦÂǚ Jʐǩ ɽ .(ÀǪŋʐǪǂǪ 254) ȻDzÊÂǤöä ȧʐʐ ǒʐȒǚǣ ȁäÀÎǪèɼä ǙÛƯ ǑĦÂş ÛǒäʐTä
.B ǡʐŸǂä ȡʒ ǦƟÅÂöä ǦǨǾǤöä ǾŸǩ ȡŋ ǵÆî ÀʓõǚÛǦÊǝÀöä ǦǨǾǤöä ǒÂʓǪèǣ

[illegible] 80 [illegible] 20 [illegible] 0.1 [illegible] **Assay**: [illegible] TS (~250 [illegible]) [illegible] 5 [illegible] .TS (~750 [illegible]) [illegible] 30.0 [illegible] 3 [illegible] 15 [illegible] .TS (200 [illegible]) [illegible] 3 VS (0.1 [illegible]) [illegible] 0.1 [illegible] 1 [illegible] .VS (0.1 [illegible]) [illegible] 4.788 [illegible] VS [illegible] $C_{10}H_{13}N_3O_5S$.

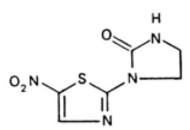
NIRIDAZOLUM

Niridazole [illegible]

Molecular formula: $C_6H_6N_4O_3S$ [illegible]

Relative molecular mass: 214.2 [illegible]

Graphic formula: [illegible]



Chemical name: [illegible]

1-(5-Nitro-2-thiazolyl)-2-imidazolidinone; CAS Reg. No. 61-57-4.

Description: [illegible]

Solubility: [illegible] TS (~750 [illegible]) [illegible]

Category: [illegible]

Storage: [illegible]

REQUIREMENTS [illegible]

General requirement: [illegible] 97.0% [illegible] 103.0% [illegible] $C_6H_6N_4O_3S$ [illegible]

:Identification tests

• A ... B ... C ... D ...

:A ... "Spectrophotometry in the infrared region" ... (43 ... 1) ...

... RS ...

:B ... "Related substances" ...

... A ... B.

:C ... 20 ... 2.0 ... R ... 2.0 ... (~80) ... TS ...

... 10 ...

:D ... 264 ...

:Heavy metals ... 1.0 ...

... "Limit test for heavy metals" ... 3 ... (127 ... 1) ...

... A ... (128 ... 1) ... 20 ...

:Sulfates ... 0.5 ... 2.0 ... (~70) ...

TS ... 8.0 ... 10 ...

... 1.0 ... (0.5) VS ...

... 0.10 ... (0.01) VS ... 2.0 ...

... (0.5) VS ... 1.0 ... 8.0 ... TS (~70) ...

...

:Solution in dimethylformamide ... 0.10 ... 10 ...

... R ...

:Sufated ash ... 3.0 ...

:Loss on drying ... 100° ... 0.6 ...

5.0 ... 3 ... 5 ...

Related substances ... R6 ... (84 ... 1 ...) "Thin layer chromatography R ... 8 R ... 12 ... 10 (A) ... R ... 4 ... 5 ... 10 (B) ... RS ... (D) ... RS ... –5– ... -2 ... 20 (C) ... RS ... 40 (... 365) ... 15 ... C ... D ... 15 ...

Assay ... 40 ... 4 ... R ... 200 ... dehydrated ethanol R ... 5.0 ... 100 ... 359 ... 1 ... RS ... $C_6H_6N_4O_3S$ ... RS ... 10 ... RS ... 0.03±0.70.

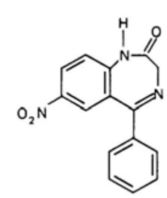
NITRAZEPAMUM

Nitrazepam

Molecular formula: $C_{15}H_{11}N_3O_3$

Relative molecular mass: 281.3

Graphic formula:



[illegible] :**Chemical name** [illegible]

1,3-Dihydro-7-nitro-5-phenyl-2*H*-1,4-benzodiazepin-2-one;
CAS Reg. No. 146-22-5.

[illegible] :**Description** [illegible]

[illegible] :**Solubility** [illegible]
[illegible] TS [illegible] 750~) [illegible]

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

REQUIREMENTS [illegible]

[illegible] %101.0 [illegible] %98.5 [illegible] :**General requirement** [illegible]
[illegible] $C_{15}H_{11}N_3O_3$

:**Identification tests** [illegible]

A: [illegible] 0.005 [illegible]
[illegible] R [illegible] 9 VS [illegible] 1) [illegible]
[illegible] 1 [illegible] 280 [illegible] 350 [illegible] 230 [illegible]
[illegible] 0.45 [illegible]

B: [illegible] 10 [illegible] 1 [illegible] R [illegible] 0.05 [illegible]
[illegible] TS [illegible] 80~) [illegible]

C: [illegible] 20 [illegible] 5 [illegible] TS [illegible] 420~) [illegible] 10 [illegible] 5
[illegible] 1 [illegible] TS [illegible] 1) [illegible] 2 [illegible]
N-(1-naphthyl) [illegible] 1 [illegible] TS [illegible] 5) [illegible]
[illegible] TS [illegible] 1) ethylenediamine hydrochloride

D: [illegible] 227 [illegible]

[illegible] :**Heavy metals** [illegible] 1.0 [illegible]
[illegible] 127 [illegible] 1 [illegible] 3 [illegible] "Limit test for heavy metals [illegible]

.ȟ/ÿǡȦʠȘȀȮɳ20 ȸȝ ǼȂÂ ɍ Ü(128 ǦĦȦÔǡ Û1 ǼŸǑǡ) A ǦȬȂÛŸ ȐǓǤù ǦŸȄǬǯǡ

.ȟ/ɳŸɳ 1.0 ȸȝ ǼȂÂ ɍ :**Sulfated ash** ǨȂŸÊʈǡ ǻȂɳȀǡ

.ȟ/ɳŸɳ 5.0 ȸɳ ȀǯȭǛ ǼȬȂǡ ȷȥȮȂ ɍ ÜǧȂȝȂè 4 ǥǼɳ °ÿ105 ǼȂȝ ȤȂʑ :**Loss on drying** ȤȄȂǱȭȂǣ ǼȬȂǡ

ȃǡȀÎȹèǡ" ȷǡȥȂȝ ǨƠ 8ȥòȥɳ ȥȽ Ȃȶȭ ǨȥȂǹ òȥȑ Ž øȂǤȹǹɍǡ ĘǤÛȂ :**Related substances** ǦǒȂÎʈǡ ǻǡȥʈǡ

ǦŸǰ8ɳ ǥǻȂȶȭ R4 ȂȮȄŸȄÊǡ ǦɳȤȽ ÿǼǺȹÊǩ Û(84 ǦĦȦÔǡ Û1 ǼŸǑǡ) "Thin layer chromatography ǦȬȄȩȀǡ ǦȬǤÛǡ

ǦĦȄȂò ɁŸȝ ŸÔȂɳ ĘǤÛȂ .ȭȀĦȹɳ øȥÛȭ R ȬȄǯȂɋǡ ǧȂȹȄèǛ ȸɳ ȐȶǱǵ 15Ș R ȷȂȹȄɳȘȀȹȂǡ ȸɳ ȐȶǱǵ 85 ȸɳ ǰȂɳȘ

(A) ɃȥƷ :R òȥȹȂǯʈǡȘ R ÿøȥȥȘøȥŸȮǡ ȸɳ ǦȂȘȂÊȹɳ ÿȂǱǵǛ ȸɳ ǰȂɳ Ž ȐǱȃȂù ȸȂȀȒȚ ƙòȥŸȚ ȸɳ ȀȹȘȀȮȄɳ 10

ǦȥȂÊɳ ƂǛ ǦĦȄȂÔǡ ȂȚȚȴ .ȀȹȬ ɄŸȄʈǡ Ž øȂǤȹǹɍǡ ǥǻȂɳ ȸɳ ÿǡȀʠȘȀȮɳ 25 (B)Ș ȀȹȬ ɄŸȄʈǡ Ž øȂǤȹǹɍǡ ǥǻȂɳ ȸɳ ɳŸɳ 25

ȧȥȥ òȥȒǡ Ž ȃǡȀÎȹèɍǡ ȔÛƯ ȌĦȂȂȘ òǡȥȚǡ Ž ȤǱȹȬ ȭȀȹǩ Ûȃǡ ȀÎȹèɍǡ ǥȀǱǵ ȸɳ ǦĦȄȂÔǡ ʈÂȹ ǼȞǣ .ȴè 12

ǦƟȂȂǡ ȬŸǩ ȸȝ ǥǼì ȀǯȭǛ ȷȥȮǩ ɍ ÛǦȄÊȄǝȀǡ ǦǨȬǤǡ òȂǯȹèȂǣ ÛA òȥŸɉǡ ȸȝ ǦƟȂȹ ǦǨȬǣ ɃǛ .(ȀȹɳȥȹȂȹ 254) ɄǱÊȂǤǡ

.B òȥŸɉǡ ȸȝ

ȒȶɯÌ ȂȂǨȂȘ R ǧȂȹȄèɉǡ ǼȂøǼȄŒǛ ȸɳ Ȭɳ 30 Ž ÛǦȄùȥǤȒɳ ǦȹȘȃȥɳ Û0.25 ǦǡȂȩ ȃǡȀØȂ :**Assay** ǦÊȂȂȬʈǡ

ǨƠ 8ȥòȥɳ ȥȽ Ȃȶȭ potentiometrically ǼȚƨǡ ȃȂȄȬɳ ǦȂȂȚȂǡ ǦÛȬȹ ȸȄȞǰ ÛVS (ò/òȥɳ 0.1) ȬȂøȥŸȭƘǤǡ

ȸɳ Ȭɳ 1 ȬȬ .(142 ǦĦȦÔǡ Û1 ǼŸǑǡ) A ǦȬȂÛǡ Û"Non-aqueous titration ɄǝȂɳŸǡ Ȕèȥǡ Ž ǥȂȂǨʈǡ" ȷǡȥȂȝ

.$C_{15}H_{11}N_3O_3$ ȸɳ ɳŸɳ 28.13 ùȥȂȮȂ VS (ò/òȥɳ 0.1) ȬȂøȥŸȭƘǤǡ Ȓƥ

NITROFURANTOINUM

Nitrofurantion ǱȋǋȺǳƐƥǋȝǋƥȺǳǁƐ

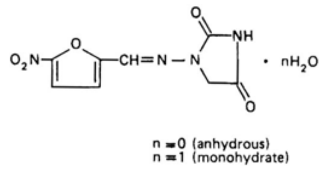
Nitrofurantion, anhydrous ȊəǲǲúǁƐ ǱȋǋȺǳƐƥǋȝǋƥȺǳǁƐ

Nitrofurantion, monohydrate ǉƐƥȹǏǋǁƐ ȹǏƟǋ ǱȋǋȺǳƐƥǋȝǋƥȺǳǁƐ

(ǧǡøǼȚǡ ǼȄǵȘ) $C_8H_6N_4O_5\,,H_2O$ Ü(ɄəȂɳɍ) $C_8H_6N_4O_5$:**Molecular formula** ǦȄȂÂƨǡ Ǧ8ȄÔǡ

.(ǧǡøǼȚǡ ǼȄǵȘ) 256.2 Ü(ɄəȂɳɍ) 238.2 :**Relative molecular mass** ǦȄǤÊȂǡ ǦȄȂÂƨǡ ǦŸȹȮǡ

:**Graphic formula** ǦȄȹȂȄǤʈǡ Ǧ8ȄÔǡ



[illegible] **Chemical name:**

1-[(5-Nitrofurfurylidene)amino]hydantoin; 1-[[(5-nitro-2-furanyl)methylene]amino]-2,4-imidazolidinedione; CAS Reg. No. 67-20-9 (anhydrous).
1-[(5-Nitrofurfurylidene)amino]hydantoin monohydrate; 1-[[(5-nitro-2-furanyl)-methylene]amino]-2,4-imidazolidinedione monohydrate; CAS Reg. No. 17140-81-7 (monohydrate).

[illegible] **Other name:** [illegible] Furadoninum.

[illegible] **Description:** [illegible]

[illegible] **Solubility:** [illegible] (~750) [illegible] R.

[illegible] **Category:** [illegible]

[illegible] **Storage:** [illegible] 25° [illegible]

[illegible] **Labelling:** [illegible]

[illegible] **Additional information:** [illegible] 271° [illegible] Stainless steel [illegible]

REQUIREMENTS [illegible]

[illegible] **General requirement:** [illegible] 98.0% [illegible] 102.0% [illegible] $C_8H_6N_4O_5$ [illegible]

[illegible] **Identification tests:**

- [illegible] A [illegible] B [illegible] C [illegible] D.

:A "Spectrophotometry in the infrared region (43 ... 1 ...)

105 ... RS ...

:B

0.3 ... 20 ... R ... 3.6

R ... 50 ... 0.12 ... 200 ... R

100 ... 5 ... 1000

0.05 ... 10

400 ... 220 ... R

0.46 ... 0.32 ... 1

367 ... 266 ... 1.42 ... 1.36 ... 266 ... 367

:C ... 0.2 ... 10 ... R

0.2 ... TS (II) ... 0.15 ... 2 ... 0.5

3 ... R

:D ... 5 ... 5 ... VS ... 0.1

Sulfated ash ... 1.0

Loss on drying ... 105 ... 10

71 ... 50

Related substances ... "Thin layer chromatography (84 ... 1 ...)

90 ... R2

10 ... R ... 10 ... R

0.25 (A) ... 10 ... R

(B) ... 1 ... A ... 100 ... R

105 ... 5

105 ... 10 ... TS

[illegible] 254) [illegible] .B [illegible]

[illegible] 0.4 [illegible] :**Assay** [illegible] 10 [illegible] 10 R [illegible] TS [illegible] 0.10 [illegible] Lithium methoxide (0.1 [illegible]) VS [illegible] "Non-aqueous titration [illegible]" B [illegible] (142 [illegible] 1 [illegible]). [illegible] (0.1 [illegible]) VS [illegible] 23.82 [illegible] $C_8H_6N_4O_5$.

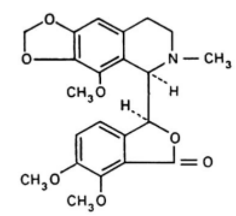
NOSCAPINUM

Noscapine [illegible]

[illegible] **Molecular formula**: $C_{22}H_{23}NO_7$

[illegible] **Relative molecular mass**: 413.4

[illegible] **Graphic formula**:



[illegible] **Chemical name**:

Narcotine; (5*R*)-5-[(1*S*)-6,7-dimethoxyphthalidyl]-5,6,7,8-tetrahydro-4-methoxy-6-methyl-1,3-dioxolo[4,5-*g*]isoquinoline; [*S*-(*R**,*S**)]-6,7-dimethoxy-3-(5,6,7,8-tetrahydro-4-methoxy-6-methyl-1,3-dioxolo[4,5-*g*]isoquinolin-5-yl)-1(3*H*)-isobenzofuranone; CAS Reg. No. 128-62-1.

[illegible] **Description**: [illegible]

[illegible] **Solubility**: [illegible] (~750 [illegible]) TS [illegible] R.

[illegible] **Category**: [illegible]

.ǞǼǶƽ ǦǝŸ8ŋ ǦĄşǻǵ Ž ƙǽǻǑèɀǍǟ ŞǻǵĀƶ :**Storage** ȸĂÂǺǪǟ

REQUIREMENTS ƘǦǜǚǙƙǳ!ƒ

ȸŋ %101.0 ȸɜ ǼĂÂĂɼş %98.5 ȸɜ ǑǞĂ ɼ ǺŋʔŸɜ ƙǽǻǑèɀǍǟ Ƀɀǫƺ :**General requirement** ȳǻǶǟ ǼŸǛǪǭǟ
.ǦǍǍǑǟ ǥǻǻţǟ ƂǗ ţɀǆǍǟǻǽ ǦǽɀÊȚ Û$C_{22}H_{23}NO_7$

:**Identification tests** ǶĭǸǋǁɛ ǀɛƥƑǴǮɛ

.Dş Cş B ǧǟøǺǪǹɼǟ ĘǦÛǩ şǗ ȻǼǵş A øǺǪǹɼǟ ĘǦÛĂ ɈǗ ǺŋǗ ●

ŏǟǍŁΣǟ ǨƠ ǦǨìɉǟ ǦǑÛǺŋ Ž ɄǝɀȒǟ ȤǪÛǟ āǺǪę" ɈǟɀǍɜ ǨƠ 8ɀòɀŋ ɀȽ ǺŁǛ øǺǪǹɼǟ ĘǦÛĂ :A
ŏǟǍŁΣǟ ǨƠ ǦǨìɉǟ ȋǺÔǪŋǟ ȤǪù ĘǽǺÛǪĂ .(43 ǦǶǺÔǟ Û1 ǼŸǑǟ) "Spectrophotometry in the infrared region
.ƙǽǻǑèɀǍŸǝ ɄǶǅǍţǟ ȤǪÛǟ ɜŋ şǗ RS ƙǽǻǑèɀǍǟǽ ǑÔǶǪÊţǟ ȤǪÛǟ ɜŋ

350ş 230 ƙǽ ǦǅɀŋǑǟɀüǗ Ž ǼȽǺȊǪĂ ǺŋǼĂɜ ÛR ǑɀǫǺǯǪţǟ Ž Ǒŋ/ŋŸŋ 0.050 ǑɀŸȚ ȋǺÔǪŋǟ ȤǪù ɃǼǦĂ :B
ǍǪŋɀǫǺǫ 263 ǦǅɀŋǑɀù Ž ʔøǫǻǗ ǼǵşǞǦĂǍǑǩ ǍǪŋɀǫǺǫ 310ş ǍǪŋɀǫǺǫ 291 ǦǅɀţǟƂɀù Ž ƙǪŁȚɜǗ ȸĂǼǵ ÛǍǪŋɀǫǺǫ
.ǞǦĂǍǑǩ 1.2 ǍǪŋɀǫǺǫ 291 ǦǅɀŋǑɀù ǼĂɜ ȋǺŁǪǟ ƂǗ ǍǪŋɀǫǺǫ 310 ǦǅɀŋǑɀù ǼĂɜ ȋǺŁǪǟ ǦǦÊǫ ŋŸǦǩ .ǞǦĂǍǑǩ
ǍǍòǗ ȼǫɀǑ ǑɀŸȚ ǑǑȊǪĂ Üǯǻɀş TS (ǒ/ȟ1760~) ǑĂøɀǺŸÊǟ ȐƤ ȸŋ Ǒŋ 0.5 ǦǽǽǺę ŋŸŋ 10 ƂǗ 8ǺȒĂ :C
.ƙǺÊǪǟ ǼĂɜ ǞǆɀÊǍǍǽ ǦǍǅǍǟ Žş ǍƥǗ ǴǦÔĂ ÛǍȒǹǬǑ āøǺȓ

.°ȳ175 ǦǽǽǺę øǺƬÔǫɼǟ ǥøǟǍǵ ǦǅøǺ :D

øɀŸȭşøǼǪȽ ȐƤ Ž ǑɀŸǂǟ ȸŋ Ǒŋ/ŋŸŋ 20 ȳǼǺǪÊĂ :**Specific optical rotation** ɄɜɀǍǟ ɃǍÔǦǟ ǍĄşǼǪǟ
.$[a]_D^{20°C}$ = + 42 to +°48 ;VS (ǒ/ǒɀŋ 0.1)

.ȟ/ŋŸŋ 1.0 ȸɜ ǼĂÂĂ ɼ :**Sulfated ash** ǨǺŸÊţǟ ǻǺŋǍǟ

.ȟ/ŋŸŋ 10 ȸŋ ǍǯȭǗ ǼǑǺĂĂ ɼ Û°ȳ105 ǼĂɜ ǨǽǺǫ ɈǍş ƂǗ ȤǺƶ :**Loss on drying** ȤǪǍǅǪǟǽ ǼǑǺǟ

ǦǑǪęǍǟ ǦǑǦÛǟ āǟǍȊǪèǟ" ɈǟɀǍɜ ǨƠ 8ɀòɀŋ ɀȽ ǺŁǛ øǺǪǹɼǟ ɃǍƶ :**Related substances** ǦǝǺȊţǟ ǻǟɀţǟ
45 ȸŋ ǰĂÂŋş ǦŸǞ8ŋ ǥǻǺŁȭ R5 ǺǑǪŸÊǟ ǦŋŸȽ ȳǼǺǪÊǩ Û(84 ǦǶǺÔǟ Û1 ǼŸǑǟ) "Thin layer chromatogrphy
ǺǪɀŋɉǟ ȸŋ ȳɀǅǵ 3ş TS (ǒ/ȟ750~) ǑɀǫǺǯĂǬǟ ȸŋ ȳɀǅǵ 7ş R ȸĂɀǒɀÛǟ ȸŋ ǞŁǅǵ 45ş R ɈɀǪèɉǟ ȸŋ ǞŁǅǵ
:TS (ǒ/ȟ750~) ǑɀǫǺǯĂǬǟ Ž ƙǒɀŸȚ ȸŋ ǍǪşǍǑǪŋ 10 ǦǶǪǍò ʔŸɜ ǮÔǍǺŋ ĘǦÛĂ .ȭǍǶǪŋ øɀÛȭ TS (ǒ/ȟ260~)
ǦǶǪǺÔǟ ɜɀø ǼǶǽ .ǍǪǑ ɄǪţǟ Ž øǺǪǹɼǟ ǥǻǺŋ ȸŋ ŋŸŋ 0.20 (B)ş ǍǪǑ ɄǪţǟ Ž øǺǪǹɼǟ ǥǻǺŋ ȸŋ ŋŸŋ 20 (A) Ƀɀƺ
ǑɀȓŽ āǟǍȊǪèɼǟ ǗǗƯ ǑǶǍĂş ÛVS (ǒ/ǒɀŋ 0.1) ǻɀǪǍǽ ǽǍǩ ÛǑǟɀȚǟ Ž ȤǅɀǑ ǑǍǪǩ Ûāǟ ǍȊǪèɼǟ ǥǍǅǵ ȸŋ
.B ǑɀŸǂǟ ȸɜ ǦΘǍǍǟ ǑŸǩ ȸɜ ǥǼì ǍǯȭǗ ÛǦǪÊǪǍǟ ǦǨǑǦǟ ǑǍǯǪèǍǽ ÛA ǑɀŸǂǟ ȸɜ ǦΘǺǫ ǦǨǑǽ ǦǍǗ ɈɀǑǩ ɼ .øǺƬǍǟ

ÛǵÛŸǚ ǘǵǼ ÛR1 ƟDzŸǃöä ÕǛǪèɟä Ȑƥ ȸ Ǒ 40 Ž ÛǦǘǵǦȒŋ Ǵɕšǵ Ûȟ0.5 Ǧää ǡäØ :**Assay** ǦÊÕţä

Non- ƟǝȘŸöä Ùèǵöä Ž ǥȞţä" ȷäǵ ǨƠ Ȣǵòǵ ǵȽ Ȧȶõ VS (ȯ/ȯǵ 0.1) ÕøǵŸõǨǦöä Ȑƥ Ȝ ÄȞş VS (ȯ/ȯǵ 0.1) ÕøǵŸõǨǦöä Ȑƥ ȸ Ǒ 1 Ǒõ .(142 ǦHÔöä Û1 ǼŸÕä) A ǦÕÛöä "aqueous titration

.$C_{22}H_{23}NO_7$ ȸ Ȝ 41.34 ǘǵÒ

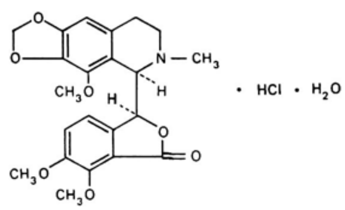
NOSCAPINI HYDROCHLORIDUM

Noscapine hydrochloride DžǏǦƑǀƨ ǋǆ ǫƥǋǂǀǋƥǫǈ

$C_{22}H_{23}NO_7$,HCl,H_2O :**Molecular formula** ǦǢȂƨä Ǧ8Ǣ Ôöä

467.9 :**Relative molecular mass** ǦǢǦÊöä ǦǢȂƨä ǦŸǪÒöä

:**Graphic formula** ǦǢɸǦţä Ǧ8ǢÔöä



:**Chemical name** ƟǝȽǢÒöä ȴèɾä

Narcotine hydrochloride monohydrate; (5*R*)-5-[(1*S*)-6,7-dimethoxyphthalidyl]-5,6,7,8-tetrahydro-4-methoxy-6-methyl-1,3-dioxolo[4,5-*g*]isoquinoline hydrochloride monohydrate; [*S*-(*R**,*S**)]-6,7-dimethoxy-3-(5,6,7,8-tetrahydro-4-methoxy-6-methyl-1,3-dioxolo[4,5-*g*]isoquinolin-5-yl)-1(3*H*)-isobenzofuranone hydrochloride monohydrate; CAS Reg. No. 912-60-7 (anhydrous).

.ǦHäÀöä ȻǼ ÛȐǢǕ Ƀøǵǚ ȧǵHÊŋ şǕ Ûȷǵöä Ǧǵ ǧäøǵǚ :**Description** ǵòǵöä

Ž ǛŸȶ ǡäşǽ Ƙǆ ÜR ÿøǵşøǵŸÒöäş TS (ȯ/ȟ750~) ȯǵɸǃqäş ǒȶä Ž ȷǽşØöä Ȁǵ :**Solubility** ǦɸǽşØöä

.R ƘǪɟä

.ȯȞÊŸö ǻȒŋ ǒäşǻ :**Category** ǦÀöä

.ǒǵȒöä ȸ ʔȶ ȷş ÛǛǼDZ ǦÕŸ8ŋ ǦşǴ Ž ƙǽÒèǵöä ǼøǵŸõşøǼȽ ȘǴ Ǽƶ :**Storage** ȸÂǾöä

.ǦǘÀǪÊŋ ǥȋ ƙǽÒèǵöä ǼøǵŸõşøǼȽ :**Additional information** ǦǵȓǕ ǧȘǵŸȟ

ȡ3 ÆĀÂĀ ɍʂ %98.5 ȡ3 ŌŌĀ ɍ Āɳ ƙǟȦÒèȥĀöä ÆĀøȥŸȭʂøÆĘȽ Ƀȥǫʒ :**General requirement** ȳĀĤöä ÆŸÛǫʈä

.ǦĀĀŎä gåĀʈä БǗ ʈȥǄĀöĀæ ǦæȥÊȚ Û$C_{22}H_{23}NO_7$,HCl ȡɳ %101.0

:**Identification tests** ƕǏǋǊǁƐ ǀƐþƑǤǐǁƐ

.Dʂ Cʂ B ǧäøĀǪǹɍä ʂǗ Dʂ A ȷäøĀǪǹɍä ĘǦÛĀ ȷǗ ĀɳǗ ●

.R ȳøȥȥʂøȥŸȭ ȡɳ Ōɳ 10 ʒɳ ʓĀƗʂ ÛTS (ȯ/ȟ100~) ĀǢǫȥɳɉĀæ ȯȥŸǂä ȷȥǊǾƗʂ ÛǑĀɳ Ōɳ 10 Ž ȟ0.1 āäØĀ :A

Ȣ ĀȒĀ ÛɄəĀɳ ȳĀþ Ž ǨǦĀǑǨ ȢĀĀƨä ɁøǫǴ ǦǵĀ ǐĀöä ĀǺǦǨ .ǴǐĀʂ ÛǑĀɳ Ōɳ 5 øæ ŌÊȢĀ ÛȳøȥȥʂøȥŸÒöä ǦǑǦù ŌÔĀǨ

ȥȽ ĀƫȭǦĀĀŎä ǦǑĀƫǯöä ȳäÆǺǫèĀæ øĀǪǹɍä ĘǦÛĀ .Ȣ ĀĀƨä Ɂøǫǵ ĀǺǦǨʂ ÛR ǒĀʈä ʈʂÂøĀɳ ȯȥǫĀǯĀɋä ȡɳ Ōɳ 1

"ophotometry in the infrared region ǒäĀƫΣä ǨƠ ǦǨǐɉä ǦǑÛĀɳ Ž ɄəȥȒöä ȤĘÛöä âĀǢȩ" ȷäȥĀʒ ǨƠ Ȣȥòȥɳ

ʒɳ ʂǗ RS ƙǟȦÒèȥĀöä ȡʒ ǰǨĀĀöä ȤĘÛöä ʒɳ ǒäĀƫΣä ǨƠ ǦǨǐɉä îĀÔǫɳä ȤĘù ĘæĀÛǫĀ .(43 ǦɄĀÔöä Û1 ÆŸŎä)

.ƙǟȦÒèȥĀŸö ɄǨǄĀʈä ȤĘÛöä

ȯȥŸǂä äØȽ ȡɳ Ōɳ 1 ǨȒĀǗ ȤĀƩ Ż ÜR ȯȥǫĀǯĘʈä ʒɳ Ōɳ 100 БǗ TS (ȯ/ȟ35~) ĀǢǫȥɳɉä ȡɳ Ōɳ 5 ȤĀƩ :B

ĀɳÆĀʒ ÛȯȥǫĀǯɳ/Āǫȥɳǂ ȡɳ ĀȒǂä ǰĀĀʈä Ž Ōɳ/ŋŸɳ 0.050 ȯȥŸȚ îĀÔǫɳä ȤĘù ɃÆǦĀ .R ȯȥǫĀǯĘʈĀæ Ōɳ 100 БǗ

ĀǪɳȥǫĀǫ 310ʂ ĀǪɳȥǫĀǫ 291 ǦǄȥʈä Бäȥù ÆĀʒ ƙĘƫȚʒǗ ȡĀÆǴ ÛĀǪɳȥǫĀǫ 350ʂ ĀǪɳȥǫĀǫ 230 ƙæ ǦǄȥɳ ȯäȥùǗ Ž ÆȽĀĪĀ

БǗ ĀǪɳȥǫĀǫ 310 ǦǄȥɳ ȯȥù ÆĀʒ îĀƫǪöä ǦǦÊǫ ǳʂäĀǪǨ .ĀǪɳȥǫĀǫ 263 ǦææĀȩ ǦǄȥʈä ȯȥù ÆĀʒ ɁøǫåǗ ǨÆǴʂ ǨǦĀǑǨ

.1.3ʂ 1.2 ƙæ ĀǪɳȥǫĀǫ 291 ǦǄȥɳ ȯȥù ÆĀʒ îĀƫǪöä

ǰǪĀĀ Ǖʒ Âƨʂ TS(ȯ/ȟ 1760~) ȬĀøȥĀŸÊöä ȐÞ gĀÛȩ ĀǫǗ gĀÛȩ ȢĀȒĀ ÛȢĀǹ ȡɄǒ Ž ȟ0.1 ǦææĀȩ ʒȑȥĀ :C

.ƙǺÊǫĀæ ɄǄÊĀĀǦöä БǗ ǦĀĀǮĀöä Žʂ Āþɉä БǗ ÆŸŌĀĀ ÛĀȒƯ ĀĀòǗ ȷȥǒ

General ǦɳĀĤöä ȢäĀȞǫèɍä ǧäøĀǪǹä" ȷäȥĀʒ ǨƠ Ȣȥòȥʈä A Ōʒ ĀĀǪöä Ōɳ/ŋŸɳ 20 ȯȥŸȚ ɄÛȞĀ :D

.(121 ǦɄĀÔöä Û1 ÆŸŎä) ǧäÆĀøȥŸÒŸö ĀĘƫȭ "identification tests

ȬĀøȥŸȭʂøÆĘȚä ȐÞ Ž Ōɳ/ŋŸɳ 20 ȯȥŸȚ ȳÆǺǫÊĀ :**Specific optical rotation** Ʉʒ ȥĀöä ɃĀÔǦöä ĀĀʂÆǫöä

.$[a]_D^{20°C}$ = + 38.5 to + 44.0° ÜǦĀĀŎä gåĀʈä БǗ ʈȥǄĀöĀæ ÆÊƠʂ VS (ȯ/ȯȥɳ 0.01)

.ȟ/ŋŸɳ 1.0 ȡʒ ÆĀÂĀ ɍ :**Sulfated ash** ǨĀŸÊʈä ǻĀɳĀöä

.ȟ/ŋŸɳ 65 ȡɳ ĀǯȭǗ ÆŌĀöä ȷȥÒĀ ɍ Û°ȳ105 ÆĀʒ ǨæĀǫ ȷàʂ БǗ ȤĀƶ :**Loss on drying** ȤĘĀǄǫŌĀæ ÆŌĀöä

ǦŌĘȩĀöä ǦŌǦÛöä āäĀĪǫèä" ȷäȥĀʒ ǨƠ Ȣȥòȥɳ ȥȽ ĀƫȭøĀǪǹɍä ɃĀƶ :**Related substances** ǦǒĀĪʈä ǻäȥʈä

45 ȡɳ ǰĀĀɳʂ ǦŸǨȢɳ gåĀƫȭ R5 ĀÒĘŸÊöä ǦɳŸȽ ȳÆǺǫÊǨ Û(84 ǦɄĀÔöä Û1 ÆŸŎä) "Thin layer chromatogrphy

[illegible] 3 [illegible] TS (750~) [illegible] 7 R [illegible] 45 R [illegible] TS (750~) [illegible] 10 [illegible] TS (260~) [illegible] 0.20 (B) [illegible] 20 (A) [illegible] VS (0.1) [illegible]

.B [illegible]

[illegible] 7 [illegible] 50 [illegible] 0.5 [illegible] :**Assay** [illegible] TS [illegible] 10 [illegible] R1 [illegible] 3 R Non-aqueous [illegible] VS (0.1) [illegible] 44.99 [illegible] VS (0.1) [illegible] 1 [illegible] (142 [illegible] 1 [illegible]) A [illegible] "titration .$C_{22}H_{23}NO_7$,HCl [illegible]

NYSTATINUM

Nystatin [illegible]

Streptomyces [illegible] *noursei* [illegible] .A_1 [illegible]

.CAS Reg.NO.1400-61-9 [illegible] :**Chemical name** [illegible]

[illegible] :**Description** [illegible]

[illegible] R [illegible] TS (750~) [illegible] :**Solubility** [illegible] .R [illegible] R [illegible]

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible] .°5 [illegible]

[illegible] :**Additional information** [illegible] %1 [illegible]

[illegible] 1 [illegible] 4400 [illegible] :**General requirement** [illegible]
.[illegible]

:**Identification tests** [illegible]

[illegible] 0.10 [illegible] :A [illegible] 50 [illegible] 5 R [illegible] R [illegible] 100 [illegible] 1 [illegible] 100 [illegible] R [illegible] 305 [illegible] 291 [illegible] 350 [illegible] 240 [illegible] 291 [illegible] 319 [illegible] 305 [illegible] 319 [illegible] 0.73 [illegible] 0.61 [illegible] 305 [illegible] .0.96 [illegible] 0.83 [illegible]

[illegible] R [illegible] 0.1 [illegible] 2 [illegible] 2 [illegible] 5 [illegible] 30 [illegible] :B [illegible] TS [illegible] 100 [illegible].

[illegible] °60 [illegible] :**Loss on drying** [illegible] .[illegible] 50 [illegible] 5 [illegible] kPa 0.6

[illegible] 10 [illegible] 0.3 [illegible] :**pH value** [illegible] .8.0-6.5

[illegible] :**Assay** [illegible] .(155 [illegible] 1 [illegible]) "Microbiological assay of antibiotics *Saccharomyces cerevisiae* [illegible] 6.2-6.0 [illegible] Cm3 [illegible] 2-1 [illegible] 300 [illegible] 25 [illegible] (NCYC 87; ATCC 9763) [illegible] 75 [illegible] .°33-29 [illegible] 1 [illegible] 200 [illegible] 10 [illegible] 50 [illegible] R [illegible] fiducial [illegible] .TS3 [illegible] 6.0 [illegible] %105 [illegible] %95 [illegible] estimated potency (P = 0.95) [illegible] limits [illegible] 4400 [illegible] (P = 0.95) [illegible]

[illegible] 1 [illegible]

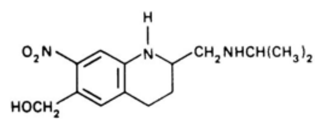
OXAMNIQUINUM

Oxamniquine [illegible]

$C_{14}H_{21}N_3O_3$:**Molecular formula** [illegible]

279.3 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

1,2,3,4-Tetrahydro-2-[(isopropylamino)methyl]-7-nitro-6-quinolinemethanol; 1,2,3,4-tetrahydro-2-[[(1-methylethyl)amino]methyl]-7-nitro-6-quinolinemethanol; CAS Reg. No. 21738-42-1.

[illegible] :**Description** [illegible]

[illegible] R [illegible] R [illegible] R [illegible] :**Solubility** [illegible]

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

REQUIREMENTS [illegible]

[illegible] %97.0 [illegible] :**General requirement** [illegible]
[illegible] $C_{14}H_{21}N_3O_3$ [illegible] %103.0

:**Identification tests** [illegible]

- [illegible] C [illegible] B [illegible] A [illegible]

spectro- [illegible] :A [illegible] "photometry in the infrared region [illegible] (43 [illegible] 1 [illegible]) [illegible]

.ƙȮƗƞǰÊõşǬǒ ǕǶǅǰƫǎ ǽƗÛǎǎ ȝƞ şǕ RS ƙȮƗƞǰÊõşɟǎ ȸȝ ǰǰǎ ǽƗÛǎǎ

Ȑƥ ȸƞ Ōƞ 0.5 ǦǎǎǰǤş ǒǰƞ Ōƞ 1.0ş R ȪɊÂǎǎ ȧǶȞÊƞ ȸƞ ƞǰƞ 10 ǦƗȶõ ƞǰƞ 10 ƂǕ ȣǰȒǍ :B
ǨǍǰǬ ȸƞ Ōƞ 1 ȣǰȒǍ ÛƗƗƨǰǂ ǻǍǍ ÛȨǝǰǻ 5 ǵƗƞ ǕǝǰƞȳǰƥŽȸǺÊǍ .TS (ȯ/ȟ250~) ȪǍøǶǰõşøƗƗǎ
0.5 ȣǰȒǍ .TS (ȯ/ȟ50) ȪƗƞǰǰǶÊǎǎ Ȑƥ ȸƞ ǦƗǶǰõ ǦƗȶõ ǦǶǰȓǚǂ ǨǍǰǬǰǎǎ ƗǍǎ ȯǎǰǍş ÛTS (ȯ/ȟ100) ȳǶǍǻǶÔǎǎ
ÛTS (ȯ/ȟ80~) ȳǶǍǻǶÔǎǎ ƗƗÊõşøƗƗ ȸƞ Ōƞ 2.0ş TS1 ȯǶǯǰɊ -2 ȸƞ Ōƞ 0.5 ȸƞ ǰǍÂƞ ƂǕ ǰǰǰǎǎ ȯǶǰɉǎ ȸƞ Ōƞ
.ƂǰȪǨǰǂ -Ȁƥǚ ɈǶǎ ǰǬǍǍ

.°ȳ151 ǦǎǎǰǤ øǰƗÔɊɍǎ ǵøǎǰǵ ǦǅǶøǻ :C

øǰǦǬȵɍǎ" ɈǎǶǍȝ ǨƠ ȣǶȍǶƞ ǶȽ ǰȶõ øǰǦǬȵɍǎ ȯǶǰƮ ƘȒȞǬǒ ȟ0.5 ȳƗǺǬÊǍ :**Heavy metals** ǦǰƗȪǯǎǎ Ɉǻǰȟȶǎ
ǦǰƗȪǯǎǎ Ɉǻǰȟȶǎ ɁǶǬƮ ƙȟǍ Ü(127 ǦȞǰÔǎǎ Û1 ƗǰŎǎ) 3 ǒǎǰǅɋǎ "Limit test for heavy metals ǦǰƗȪǯǎǎ ɈǻǰȟȶǰǒɃƗƩǎ
.ȟ/ȳǎǰȡşǰȮƞ 50 ȸȝ ƗǍÂǍ ɍ Ü(128 ǦȞǰÔǎǎ Û1 ƗǰŎǎ) A ǦȪǍǰÛǰǒ ǰȪǦǜ

Ōƞ 30ş FeTS (ȯ/ȟ250~) ȪǍøǶǰõşøƗƗǎ Ȑƥ ȸƞ Ōƞ 5 Ž ǦǒǰȶǯǎǎȁǎǰØǩş ǻǍǍ Üȟ1.0 Ɨƞǰǰ :**Iron** ƗǍƗƩǎ
Û1 ƗǰŎǎ) "Limit test for iron ƗǍƗƩǎ ŌǅɟɃƗƩǎ øǰǦǬȵɍǎ" ɈǎǶǍȝ ǨƠ ȣǶȍǶƞ ǶȽ ǰȶõ ȯǶǰɉǎ ŽǰȟǍ .ǒǰƞ
.ȟ/ȳǎǰȡşǰȮƞ 50 ȸȝ ƗǍƗƩǎ ɁǶǬƮ ƗǍÂǍ ɍ Ü(129 ǦȞǰÔǎǎ

.ȟ/ƞǰƞ 2.0 ȸȝ ƗǍÂǍ ɍ :**Sulfated ash** ǨǰǰÊȶǎ ǻǰƞǰǎǎ

Determination of water by ǰÎƗ ȯøǰõ ǦȪǍǰÛǂ ǒǰȶǎ ƙƗǩ" ɈǎǶǍȝ ǨƠ ȣǶȍǶƞ ǶȽ ǰȶõ ƙȟǍ :**Water** ǒǰȶǎ
ǒǰȶǎ ɁǶǬƮ ƗǍÂǍ ɍ Üǵǻǰȶǎ ȸƞ ȟ0.5 ǦǎǎǰǤ ȳƗǺǬÊǍ Û(145 ǦȞǰÔǎǎ Û1 ƗǰŎǎ) A ǦȪǍǰÛǎǎ "the Karl Fischer method
.ȟ/ƞǰƞ 20 ȸȝ

Ȩǰȟȶǎ ǒǰȽǰǂ ÜR ɈǶǂǰȮǎǎ ƗƗÊõǕ ǕǝǰǬ ȸƞ Ƃǰʅǎ ǒǰȶǎ ȸƞ Ōƞ 10 ȝƞ ȟ0.1 ǯǰɫ :**pH value** ǒǰȽǰǦǎǎ ȴƗǤ
.10.0 - 8.0

ǦȪƗǤǰǎǎ ǦȪǦÛǎǎ ȁǎǰÎǬȅǎ" ɈǎǶǍȝ ǨƠ ȣǶȍǶƞ ǶȽ ǰȶõ øǰǦǬȵɍǎ ȨǦÛǍ :**Related substances** ǦǒǰÎȶǎ ǻǎǶȶǎ
ǦǰǰȣȶǎǦȞƗǰÔǎǎ) Ǧǰǰȣƞ ǵǻǰȶõ R6 ǰȮƗǰƗÊǎǎ ǦƞƳȽ ȳƗǺǬÊǩ Û(84 ǦȞǰÔǎǎ Û1 ƗǰŎǎ) "Thin layer chromatography
ȸƞ ȴǅǵ 2ş R ɈǰÊȮƗǎ ȸƞ ȳǶǅǵ 10ş R ȳøǶǶşøǶǰȮǎǎ ȸƞ ǰȶǅǵ 20ş (ǦǦȅǰƞ ǦǍøǰƟ øǻǰÔƞ ȸƞ ǰƳǦǤ
ȸƞ ǰǬşǰȮƗƞ 10 ǦȞƗǰȍ ɁǰȝǰƳÔǰƞ ȨǦÛǍ .ȭǰȞǬƞ øǶÛõ R ƙƞƳƗşǰşÂǰǕ ȸƞ ȴǅǵ 0.5ş R ȯǶɊǰşǰǂ-2
ǕǰƗȶǎ Ž øǰǦǬȵɍǎ ǵǻǰƞ ȸƞ ƞǰƞ 25 (A) ɃǶȜ :R ȯǶɊǰǯƗȶş R ȳøǶǶşøǶǰȮǎǎ ȸƞ ǦǍşǰÊǬƞ ȳǰǅǵǕ ȸƞ ǰǍÂƞ Ž ƙȯǶǰƮ
ǒǎǶƮǎ Ž ȝǅǬǒ ȭǰǬǩ ÛȁǎǰÎǬȅɍǎ ǵǰǅǵ ȸƞ ǦȞƗǰÔǎǎ ȝǶø Ɨȟǂ .ǰǬǒ ǕǰƗȶǎ Ž øǰǦǬȵɍǎ ǵǻǰƞ ȸƞ ƞǰƞ 0.25 (B)ş ǰǬǒ
ǦǅǶȶǎ ȯǶǜ ƗǍȝ ǦƗǅÊǰǰǦǎǎ ȧǶǶ ǦȟȉɟǎǒǶȒǂ ǰşǕ ȁǎǰÎǬȅɍǎ ǙÛƠ ȪȞǰǍ .ğǰǦǍøȶǎ ǰǺǦǩ ɁøǬǵ Ȩǝǰǻ 10 ǵƗƞ
ǰǯȭǕ ÛǦƗÊƗǝǰǎǎ ǦȟȪǦǎǎ ǒǰǯǬȅǰǂ ÛA ȯǶǰɉǎ ȸȝ ǦƟǰɊ ǦȟȪǂ ɃǕ ɈǶȮǩ ɍ .ǰǬƞǶɊǰɊ 365 ǦǅǶƞ ȯǶǜ ƗǍȝ Ż ǰǬƞǶɊǰɊ 254

.B ȯϛŶǂǟ ȸȝ ǦΘǺȂǟ ȎŶǩ ȸȒ ǥǼȉ

ǹȎǟǺè ȯǼǶǪÊȒ ǛR1 ɄDzŶǯǟ ȎǪèɉǟ ȒƥȸȒ ȎȒ30 Ž ǛǦǼüϛǦȒȒ Ǧǫşàϛȓ ǛȟO.3 ǦǟǟǺę ǡǟǾǺ :Assay ǦÊǺǺȎţǟ

ϛȽ ǺȶȎ VS (ȯ/ȯϛȒ 0.1) ȎǺǿϛŶȎǨǦǟ ȒƥȝȒ ǺǺǺǶǺ .TS ȎǪèɉǟ ȒƥǁR (oracet blue) ǨǼèǟǿşɉǟ ǦęǿǟБǛ 1 ȎȎ .(142 ǦȞǺÔǟ Û1ǼŶǑǟ) A ǦǑǺǺÛǟ "Non-aqueous titration ɄəǺţǟ Ǜèϛǟ Ž ǥǺǺǺţǟ" ȷǟϛǺȝ ǨƠ ȣϛòϛȒ

.$C_{14}H_{21}N_3O_3$ ȸȒ ȠŶȒ 27.93 ǜϛǺȮǺ VS (ȯ/ȯϛȒ 0.1) ȎǺǿϛŶȎǨǦǟ ȒƥȸȒ ȎȒ

OXYTETRACYCLINI DIHYDRAS

Oxytetracycline dihydrate ǊǏǂǀǏƨƐƥǶ Ǐƨ ǀǋǓƐ ǀƐƥǪǏǈ ǏəǺǻ

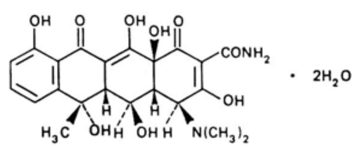
Oxytetracycline dihydrate (non-injectable) (ǊšΘǂǁ üǦǺƽ ƥǏȝ) ǊǏǂǀǏƨƐƥǶ Ǐƨ ǀǋǓƐ ǀƐƥǪǏǈ ǏəǺǻ

Oxytetracycline dihydrate, sterile !šyǊǁƐ ǛǊǏǂǀƨƐƥǶ Ǐƨ ǀǋǓƐ ǀƐƥǪǏǈ ǏəǺǻ

$C_{22}H_{24}N_2O_9$,$2H_2O$:**Molecular formula** ǦǼǺǺÂƨǟ Ǧ8ǼÔǟ

496.5 :**Relative molecular mass** ǦǼǦÊǺǟ ǦǼǺǺÂƨǟ ǦŶǪȮǟ

:**Graphic formula** ǦǼǫǺǼǦţǟ Ǧ8ǼÔǟ



:**Chemical name** ɄəǺǼȽǼȮǟ ȴèȓǟ

(4*S*,4a*R*,5*S*,5a*R*,6*S*,12a*S*)-4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,6,10,12,12a-hexahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide dihydrate; [4*S*-(4α,4aα,5α,5aα,6β,12aα)]-4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,6,10,12,12a-hexahydroxy-6-methyl-1,11-dioxo-2naphthacenecarboxamide dihydrate; CAS Reg. No. 6153-64-6 (dihydrate).

.ǦȞəǟǺǟ ǦǼȝ ǛǼǥǺȉ ǺǺòǛ ǛɃǿϛŶǟ ȧϛȞÊȒ :**Description** Ȥòϛǟ

Ž ȷǺǟşǾǟ Ǻǥ ǛTS (ȯ/ȟ 750~) ȯϛǫǺǯǺǛ Ž ǋǼŶę ǡǟşǟ ǛǑǺţǟ Ž ǹǼǊ ȷǺǟşǾǟ ǴǼȞȉ :**Solubility** ǦǼǫǺǟşǾǟ

.ǥǺǼȽţǟ ǧǺǺϛŶȎǟş ȏϛȽΣǟ

.ɄȒϛǫǺǊ ǻǺȒȒ ǒǟşǻ :**Category** ǦǺǺǟ

.ǒϛȒǟ ȸȒ ɁȽȝ ȷǛş ǛǼǼǼǊ ǦǑŶ8ȒǦǺşǺǥ Ž ƙŶȮǼèǟǺǪǩ ɄÊȏşɉǟ ǧǟǿǼȽ ɄəǺǫ ȘǺǥ Ǽƶ :**Storage** ȸǺÂǺǪǟ

ğ ÀǴŸÛǪɳ Бΰ ÆĚĐzǪÊǩ gấÀţã ȷΰ Бΰ ʟȰȞţã ƙŸȮĚèãÀǪǩ ƟÊõşɟã ğãøÆĚŁ ƟəÀÀǫ ǦęÀÔò ƙǦǩ :**Labelling** ʟĚèɀǪöã ǦŧĚȪვ ğÀÖĚǦÛǩ Ž şΰ ĦÃÖǵ öÀÛვRò ÀTÀŧȞǪèã ȸÒƩ ȼǫΰş ʟȰȞţã ƙŸȮĚèãÀǪǩ ƟÊõşɟã ğãøÆĚŁ ƟəÀÀǫ ŎDZΰ ȸɳ ǦĚɀÀȓΰ .ɁÀǹΰ

öɀȒò ȼȓÀȞǩ ÆÀვ ƙŸȮĚèãÀǪǩ ƟÊõşɟã ğãøÆĚŁ ƟəÀÀǫ ȷɀò ʟǪȪÀ :**Additional information** ǦĚɀÀȓΰ ğÀɳɀŸȞɳ .ǦÀɀŸÕöã ÆĚÊõşøÆĚTã ŎĚöÀȞɳ ǦვÀÊæ ãÀǺǪÀş 2 ȸɳ Ŏęΰ öÀŁÀæ Ƀæ öɀŸƮ Ž ÆÊÀÀ .Ƀɀę Ȅ ƽ

REQUIREMENTS ƘǦȟĩƱƙďž!ƒ

920 ȸვ ŎȪÀ ғ Àɳ ɁŸვ ƙŸȮĚèãÀǪǩ ƟÊõşɟã ğãøÆĚŁ ƟəÀÀǫ Ƀɀǫʒ :**General requirement** ÿÀȞöã ÆŸÛǪţã .ǦĚəÀɳŸöã gấÀţã Бΰ ţɀDZÀöÀæ ǦæɀÊƮ ÛɳŸɳ 1 Ŏõ Ž ƙŸȮĚèãÀǪǩ ƟÊõşɟã ȸɳ Ǧĕşấ gÆǵş

:**Identification tests** ȟɩǸǋǇɛ ɭ ɛƥƑƓǬɛ

"Thin layer chromatography ǦȪĚęÀöã ǦȪǦÛöã ããÀÎǪèã" ȷãɀÀვ ǨƠ Ȣɀòɀɳ ɀȽ Àŧõ øÀǦǪǹғã ĘǦÛÀ :A ȸɳ ȟ25 Бΰ ȢÀȒÀ :ƟŸÀ Àŧõ ÀȒʒ (ÀȽɀƨã ȄĚõ) øɀȢŸĚÊĚȮöã ŎŸȢɳ ÿãÆǺǪèÀæ Û(84 ǦȞÀÔöã Û1 ÆŸÕã) ƟəÀÀǫ ğÀǪÀÆÀΰ ȸɳ Ŏɳ 47.5ş R öşƘĚŸȢöã ȸɳ Ŏɳ 2.5 ȸɳ Ȥöǘɳ ǰÀÂɳ ȸɳ Ŏɳ 50 R1 (ÀȽɀƨã ȄĚõ) øɀȢŸĚÊĚȮöã ȭÀǪǩş ǰÀÂţã ãØõ ǦȞĚÀÔöã ŎǻȢǩ .TS (ò/ȟ100~) ÀĚǫɀɳɟÀæ 7 öÀŁÀæ Бΰ ĦÕæÀè ǴȞÔɳ VS (ò/öɀɳ 0.1) ÿɀÀấɀÔöã øɀÛõ .ĦɀǦȪɳ ĦŸÔɀ ƟÛȞÀ Àɳ ĦĚɀÀõ ÀƬɀÀÀDZ ȷɀȮÀ ɁøǪǵ şΰ ÛĦǦÀÀȪǩ ǦȪĚęấ 90-70 gÆɳ ǦɀÀȢöã gøãÀǵ ǦDZøấ Ž ȤDZǪò ʟDZǵş R ÿøɀɀşøɀŸȮöã ȸɳ ʟDZǵ 2ş R ŎĚȜÀǭã ğÀǪĚèΰ ȸɳ ʟDZǵ 2 ȸɳ Ȥöǘɳ ǰÀÂɳ ȸɳ Ŏɳ 200 ǾǹǘÀ ÛȭÀȞǪɳ 7 öÀŁÀæ Бΰ ĦÕæÀè gãɀÊɳ VS (ò/öɀɳ 0.1) ÿɀÀấɀÔöã ƟəÀÀǫ ğÀǪÀÆÀΰ ȸɳ Ŏɳ 25 ვɳ ğȜÀł ÛR ȷɀǪĚèɟã ȸɳ Æǵş ŎĚöÀƮ ȸɳ ÀǪöşÀȮĚɳ 1 ǦȞĚÀò ɁŸვ ĦÔÀÀɳ ĘǦÛÀ .ɁŸÀÊöã ǦȪǦÛöã ÿÆǺǪÊǩş ÛÆęÀǪò ȭÀǪǩ ÛTS (ò/ȟ100~) ÀĚǫɀɳɟÀæ ƟÊõşɟã ğãøÆĚŁ ƟəÀÀǫ ȸɳ ȠŸɳ 0.50 (B)ş ÀǪò ƟŸĚţã Ž øÀǦǪǹғã gấÀɳ ȸɳ ȠŸɳ 0.50 (A) Ƀɀʒ :R öɀǫÀȜĚţã Ž ǦǫŸǫ 0.50ş ÀǪò ƟŸĚţã Ž RS ƙŸȮĚèãÀǪǩøɀŸÕöã ÆÀøɀŸõşøÆĚŁ ȸɳ ვɳ 0.50 ȸɳ ǰÀÂɳ (C)ş ÀǪò ƟŸĚţã Ž RS ƙŸȮĚèãÀǪǩ ƟŸĚţã Ž ƙŸȮĚèãÀǪǪöã ÆÀøɀŸõşøÆĚŁ ȸɳ ȠŸɳ 0.50ş ÀǪò ƟŸĚţã Ž RS ƙŸȮĚèãÀǪǩ ƟÊõşɟã ğãøÆĚŁ ƟəÀÀǫ ȸɳ ȠŸɳ ÛTS (ò/ȟ260) ÀĚǫɀɳΰ gÀǸΰ Бΰ ôĦȞǩ ÛöãɀTã Ž ȤDZǪò ȭÀǪǩ ããÀÎǪèғã gÀDZǵ ȸɳ ǦȞĚÀÔöã ţÂǫ ÆȞæ .ÀǪò öɀŸɫã ȸვ ǦƟÀÀöã ǦĚÊĚəÀöã ǦȞȪǦöã ĘæÀÛǪǩ .(ÀǪɳɀǫÀǫ 365) ǦĚDZÊÀÀǦöã ȧɀɀ ǦȞȉɟã öɀȓ Ž ããÀÎǪèғã ÙÛƯ ȰȞÀÀş ãÀÎǪèғã ÙÛƯ ÀȚȚÀ ɃÀɳ ĦęşÆÔɳ øÀǦǪǹғã ǼȞÀ ғ . B öɀŸɫã ȸვ ǦƟÀÀöã ȭŸǩ ვɳ gÆÎöãş ÀȚȚţãş ვęɀţã Ž A .dzɀȓɀæ ǦŸÔÀÀɳ ʒȪæ ǦǫŸǫ C öɀŸɫã ȸვ ǰǨÀÀöã

ÀÀòΰ Бΰ ÀȞȢǪÀ ÛĘɳÀȡ ÀƥΰȷɀòǰǪÀÀ ÛTS (ò/ȟ1760~) ȭÀøɀÀŸÊöã Ȓƥ ȸɳ Ŏɳ 2 ȢÀȒÀ ȠŸɳ 1 ǦæãÀę Бΰ :B .öÀţã ȸɳ Ŏɳ 0.1 ǦɀÀȓΰ ÆÀვ

0.25 : **Specific optical rotation** 60 25 (0.1 VS)

$[a]_D^{20°C}$ = –203 to -216°.

5.0 : **Sulfated ash**

Determination of water by : **Water** "the Karl Fischer method" A (1454) 0.25

75 40.

7.5-4.5 10 : **pH value**

: **Absorption in the ultraviolet region** (0.1 VS) 20

230 400 268 353

1 353 0.54 0.58.

2.0 : **Light-absorbing impurities**

(1 VS) 99 R

0.25 430 1

(1 VS) 99 R 10

0.20 490 1.

: **Assay**

Bacillus (*a*) (155 1) "Microbiological assy of antibiotics

6.6-6.5 Cml (NCTC 8241 or ATCC 14884) *pumilus*

20 2 4.5 TS

(ATCC 11778) *Bacillus cereus* (*b*) 39-37°

4.5 TS 6.0-5.9 Cml

33-30° 2 0.5

%95 estimated potency (*P* = 0.95) fiducial limits

(*P* = 0.95) %105

900.

!ĭšyⅡɛ Džĭǂǀĭƨɛþŀŀ Ĭƨǀǌ ǀɛþϭĭǀj Ĭǝƒǁ ħĭʒƑҬǝ ǀƑǂƯƗDž
Additional Requirements for Sterile Oxytetracycline Dihydrate

Test Ǵὺ̀ÀȦţ ǴŁȶÊöä øȦϘǹä" ȷäζȦʒ ǨƠ Ȣζȍζɳ ζŁ Ȧȶõ øȦϘǹɼä ĘǴÛΛ :**Undue toxicity** Ǵὺ̀ÀȦţ ǴŁȶÊöä ǥǻȦţ ȡɳ ʒɳ 40 āäØΛ :ɄŸΛ Ȧȶõ ÀȒϒ ȯζŸϒ ȡɳ Ōɳ 0.5 ӯǼǺϘÊΛ Û(165 ǴΗȦÔöä Û1 ǼŸŎä) "for undue toxicity ʔŸʒ ȯζÔΗŸö R ǈŐĤɳ ŏȦɳ ȡɳ ǴŁζȦõ ǴŁȶȮǝ ȤȦƸʂ VS (ȯ/ȯζɳ 0.1) ŌΛøζŸõʂøǼŁΤä Ȑƥ ȡɳ Ōɳ 2.0 Ž ǥƎϘǺţä .Ōɳ 20

Û1 ǼŸŎä) "Sterility testing of antibiotics ǴΛζŁΣä ğäǻȒȶŸö ǴɳȦŐĤöäøȦϘǹä" ɄøǴŸΛ :**Sterility** ǴɳȦŐĤöä R (macrogol *P*- ȡɳ Ōɳ 1 ʔŸʒ ɃζϘʒ ȤȦƯ ȯζŸϒ ӯǼǺϘÊΛʂ ǴŁǏÀϘöä ŏȦÎȡ øȦϘǹä ŏäÀDZÜ ĘǴÛΛ Û(162 ǴΗȦÔöä .TS (ȯ/ȟ1) ȷζϘǴöä ȡɳ Ǽǵäʂ ÀϘö Ž isooctylphenyl ether)

!ĭšyⅡɛ üƑDžyƗƨŰɛ üШŬ Džĭǂǀĭƨɛþŀŀ Ĭƨǀǌ ǀɛþϭĭǀj Ĭǝƒǁ ħĭʒƑҬǝ ǀƑǂƯƗDž
Additional requierments for Oxytetracycline dihydrate for sterile use

Test for non injectable ȡŐΗŸö ǥǼĤţä Ƙȡ ğäȒΗϘÊţä ǴɳȦŐʒ ŌDZɉ øȦϘǹä" ǥǻʂȦζɉ ǢŁDZϘÊΛ .(32 ǴΗȦÔöä ÛǴΛǼŸȮϙqä ǴǴÛöä Û5 ǼŸŎä) "*preparations*

øȦϘǹɼä" ȷäζȦʒ ǨƠ Ȣζȍζɳ ζŁ Ȧȶõ øȦϘǹɼä ĘǴÛΛ :**Bacterial endotoxins** ǴŁɳζϘÀƨä ǴŁŸǹäǼöä ğȦϙȦΛØöä Ü(ǴΛǼŸȮϙqä ǴǴÛöä Ž 30 ǴΗȦÔöä Û5 ǼŸŎä) "Test for Bacterial endotoxins ǴŁŸǹäǼöä ǴŁɳζϘÀƨä ğȦϙȦΛØöä ŌDZɉ .ƙŸȮèäÀϘǩ ɄÊõʂɉä ȡɳ ӯäÀȡ ɄŸŁţä Ž ǴŁöʂǻ ǥǼǵʂ 0.4 RS ɄŸǹäǼöä ȷȦΛØöä ȡɳ ʔζϘǂä äʂȦDZϘΛ ɼ

OXYTETRACYCLINI HYDROCHLORIDUM

Oxyetracycline hydrochloride Džĭǂǀĭƨɛþŀŀ Ĭƨǀǌ Ŭɛ ϭĭþǌǂǀǌþϭĭǀj

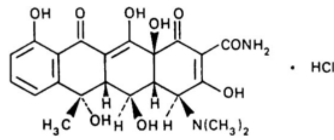
Oxyetracycline hydrochloride (non-injectable) (DžšΘǂǁ üǴƑƽ þĭʒ) Džĭǂǀĭƨɛþŀŀ Ĭƨǀǌ Ŭɛ ϭĭþǌǂǀǌþϭĭǀj

Oxyetracycline hydrochloride, sterile !ĭšyⅡɛ ÛDžĭǂǀĭƨɛþŀŀ Ĭƨǀǌ Ŭɛ ϭĭþǌǂǀǌþϭĭǀj

$C_{22}H_{24}N_2O_9$,HCl :**Molecular formula** ǴŁȦΛÂƨä Ǵ8ŁÔöä

496.9:**Relative molecular mass** ǴŁǴÊΛöä ǴŁȦΛÂƨä ǴŸϘȮöä

:**Graphic formula** ǴŁϙȦŁǴţä Ǵ8ŁÔöä



[illegible] **Chemical name**:

(4*S*,4a*R*,5*S*,5a*R*,6*S*,12a*S*)-4-(Dimethylamino)1,4,4a,5,5a,6,11,12a-octahydro-3,5,6,10,12,12a-hexahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrochloride; [4*S*-(4α,4aα,5α,5aα,6β,12aα)]-4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,6,10,12,12a-hexahydroxy-6-methyl1,11-dioxo-2-naphthacenecarboxamide monohydrochloride; CAS Reg. No. 2058-46-0.

[illegible] **Description**: [illegible].

[illegible] **Solubility**: [illegible] 45 [illegible] (~750 [illegible]) [illegible] R [illegible] R [illegible].

[illegible] **Category**: [illegible].

[illegible] **Storage**: [illegible].

[illegible] **Labelling**: [illegible].

[illegible] **Additional information**: [illegible] base [illegible] 2 [illegible].

REQUIREMENTS [illegible]

[illegible] **General requirement**: [illegible] 870 [illegible].

Identification tests [illegible]:

A: [illegible] Thin layer chromatography [illegible]

[illegible] (84 [illegible] 1 [illegible]) [illegible] 25 [illegible]

[illegible] 47.5 [illegible] R [illegible] 2.5 [illegible] 50 R1 [illegible]

[illegible] TS (100~) [illegible] 7 [illegible] VS (0.1) [illegible]

[illegible] 90-70 [illegible]

[illegible] R [illegible] 2 [illegible] R [illegible] 2 [illegible] 200 [illegible]

7 [illegible] VS (0.1) [illegible] 25 [illegible] R [illegible]

[illegible] 1 [illegible] TS (100~) [illegible]

[illegible] 0.50 (B) [illegible] 0.50 (A) [illegible] R: [illegible]

0.50 [illegible] RS [illegible] 0.50 [illegible] (C) [illegible] RS [illegible]

[illegible] 0.50 [illegible]

[illegible] TS (260) [illegible]

[illegible] A [illegible] (365 [illegible])

[illegible] B. [illegible]

[illegible] C [illegible].

B: [illegible] 1 [illegible] 2 [illegible] TS (1760~) [illegible]

[illegible] 0.1 [illegible].

C: [illegible] 0.05 [illegible] B [illegible] General

identifications tests [illegible] (121 [illegible] 1 [illegible]).

Specific optical rotation: [illegible] 0.25 [illegible]

VS (0.1) [illegible] 25 [illegible] 60 [illegible]

$[a]_D^{20°C}$ = - 188 to -200°.

Sulfated ash: [illegible] 5.0 [illegible].

Water: [illegible] Determination of water by

the Karl Fischer method [illegible] A (145 [illegible] 1 [illegible]) [illegible] 0.25 [illegible] 20 [illegible]

[illegible].

[illegible] **pH value**: [illegible] 10 [illegible] 3.0 - 2.0.

[illegible] **Absorption in the ultraviolet region**: [illegible] 20 [illegible] (0.1 [illegible]) VS [illegible] 230 [illegible] 400 [illegible] 268 [illegible] 353 [illegible] 1 [illegible] 353 [illegible] 0.54 [illegible] 0.58.

[illegible] **Light-absorbing impurities**: [illegible] 2.0 [illegible] (1 [illegible]) VS 99 [illegible] R [illegible] 1 [illegible] 430 [illegible] 0.50.

[illegible] 10 [illegible] (1 [illegible]) VS 99 [illegible] R [illegible] 1 [illegible] 490 [illegible] 0.20.

[illegible] **Assay**: [illegible] "Microbiological assy of antibiotics [illegible] 1 [illegible] 155) [illegible] (*a*) [illegible] *Bacillus pumilus* (NCTC 8241 or ATCC 14884) [illegible] Cml [illegible] 6.5-6.6 [illegible] TS 4.5 [illegible] 2 [illegible] 20 [illegible] 37-39° [illegible] (*b*) [illegible] *Bacillus cereus* (ATCC 11778) [illegible] Cml [illegible] 5.9-6.0 [illegible] TS 4.5 [illegible] 0.5 [illegible] 2 [illegible] 30-33° [illegible] fiducial limits [illegible] (*P* = 0.95) estimated potency [illegible] 95% [illegible] (*P* = 0.95) [illegible] 105% [illegible] 870 [illegible].

[illegible]

Additional requierments for Oxytetracycline hydrochloride for sterile use

Test for sterility of non injectable [illegible] "*preparations* [illegible] 5 [illegible] 32 [illegible]).

[illegible] **Bacterial endotoxins**: [illegible] "Test for Bacterial endotoxins [illegible] 5 [illegible] 30) [illegible]

.ƙŸỎèāÀǪǩ ƟÊõş ɉā ȸŋ ŷāÀɖ ƟŸŧā Ž ǴĿöşắ ǥǼǵş 0.4 RS ƟŸǹāǼöā ɈÅÀǾöā ȸŋ ʔζǪƗā àşÅDzǪÀ

Sterility testing of ǴÀζĿΣā ğāắÅȒţā ǴŋÅÕɜ øÅǴǪǹā"øǽ ǴòÅʅā ǥắşÀζɉā ƂǗ ǼĿDzǪÊÀ :**Sterility** ǴŋÅÕȞöā

.ƟəÅÎ8öā ǴĿÌÀǪöā øÅǴǪǹā öāÀDZǗ ĘĿǴÛǪǽ Û(162 ǴĦÅÔöā Û1 ǼŸŎā) "antibiotics

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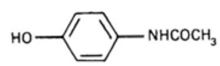
PARACETAMOLUM

Paracetamol üŇǰŽƑĬĭƨƐþƑǴ

$C_8H_9NO_2$:**Molecular formula** ǴĿÅÀÂƨā Ǵ8ĿÔöā

151.2 :**Relative molecular mass** ǴĿǴÊÀöā ǴĿÅÀÂƨā ǴŸǪỎöā

:**Graphic formula** ǴĿφÅĿǴţā Ǵ8ĿÔöā



:**Chemical name** ƟəÅĿȽĿỎöā ȴèɍā

4′-Hydroxyacetanilide; *N*-(4-hydroxyphenyl)acetamide; CAS Reg. No. 103-90-2.

.**Acetaminophen** ƙζζǼŋÅǪĿèǗ :**Other name** ÀǹǗ ȴèā

.ǴĦəāÀöā ĆǼɜ ǕɈζŸöā ȐĿǽǗ ÛɃøζŸǽ ȧζĦÊŋ :**Description** Ȥòζā

āāşǽ ƘɖǗR ɈζǪĿèɉāş TS (ȯ/ȟ750~) ȯζφÅǯÀɋā Ž ɈÅǽşǾöā Àǵ ǗŏÅţā Ž ɈÅǽşǾöā ŎĿŸę :**Solubility** ǴĿφÅǽşǾöā

.ÅĿŸȶɜ R ƘǪɉā Ž

.ʔȶΣā ắÅȒŋ ǗȸỎÊŋ :**Category** ǴÅÀöā

.ǒζȒöā ȸŋ ʔȶĦƚ ɈǗş ǕŷÅỎǵǖǽ ǴŎŸ8ŋ ǴÀşÅǵ Ž ȯζŋÅǪĿèāøÅǴöā ŞÀɜ ɈǗ Ǽƶ :**Storage** ȸÀÂÅǪöā

REQUIREMENTS ƘǴŀǖƱƙǆž!ƒ

%101.0 ȸɜ ǼÀÂÀ ɍş %98.5 ȸɜ ŎÕÀ ɍ Åŋ ʔŸɜ ȯζŋÅǪĿèāøÅǴöā Ƀζǯɜ :**General requirement** ŷÅȞöā ǼŸÛǪţā

.ǴÅāŎā ǥắÅţā ƂǗ ţζDZÀöÅǽ ǴǽζÊȚ ÛC₈H₉NO₂ ȸŋ

:**Identity tests** ƕĭŇǰŇǁƐ ƖƐþƑǴĦǪƐ

(ȯ/ȯǫ 0.1) ŌǿǶǫŏşǿǼŢ Ȅ þ ǳǫ Ōǫ 0.5 ȣ ȦȒ .R ȯǫǿǯŧ ȯǫŢ ǳǫ Ōǫ 100 Ž ȟ 0.05 ā ǿȽ :A

ǥȁ ȉ ǭǫ ȋ ȴǿ ȃ Ȍş ŏǫȒ ǳǫ ȯǫ Ȣ ʔȶʒ .Ōǫ 100 Ƀ ȯǫǿǯŧ ȯǫǫ ǻǼƨş ȯǫ ǿȽ ǳǫ Ōǫ 1 Ƀ VS

.0.88 ǻşǼ ȷǫȮǫ Ǜǫǫǿ 249 Ʉȶ Ţʒɉ ǅǫţ ȯǫȖş ḻȅ 1 ǦǿǺ ǦǬù Ǝʒ

ȷǫ ǰ ǛTS (ȯ/ȟ 25) ŌǼǼΣ Ǽǿǫŏ ȯǫŢ ǳǫ Ōǫ 0.05 ȣ ȦȒş ŏţ ǳǫ Ōǫ 10 Ž ȟ 0.1 ā ǿȽ :B

.ȧǿȁɉ Ƀ āǿȓ ɄǅȆȦ

ŏţ ǳǫ Ōǫ 10 ȣ ȦȒ ǕȨǻ ϙŸ ǥǼǫ TS (ȯ/ȟ 70~) ŌǿǶǫŏşǿǼŢ Ȅ þ ǳǫ Ōǫ 1 Ž ȟ 0.1 ʔ8 :C

ȷǫ ǰ ǛVS (ȯ/ȯǫ 0.0167) ÿǫȅǫǦ ǧǫşȍŏ Ʉǿ ȯǫŢ ǳǫ Ōǫ 0.05 ȣ ȦȒ .Ǧȅǿ ȮȮȊ ɍ ǛǻŀȘ

.(Phenacetin ƙȅǿ ǳʒ Ȃţǿ) Ȁþɉ ȷǫ Ƀ ȯǫ ɍş ǕŏȔǦ ɄǅȆȦ

.°ÿ172-168 :**Melting range** ǿȎɍ ȯƒ

ǳǫ ȶǅǵ 85 ǳǫ ǰǫş ȟ 1.0 ŌȶȆ ǿǹɍ ȯǫŢ ƘȒǿ :**Heavy metals** ǦŸŏ (ǧǿ) ȷǻţ

Limit test for ǦŸŏ ȷǻţ ŌǅɉɃΣ ǿǹɍ" ȷǫʒ ǨƠ ȣǫȍǫ ǫȽ ȶŏ ŏţ ǳǫ ȶǅǵ 15ş R ȷǫȅɉ

.ȟ/ÿȡşȮǫ 10 ȁşǅǫ ɍ Ǜ(128 ǦȮ Ȗ1 ǼŎ) A ǦȖ ÆȆɯ "heavy metals

.ȟ/ȠǫǷ 1.0 ǳǫ ȁŏ ǼǅǫǼ ɍ :**Sulfated ash** ǨȆţ ǻǫȍ

5.0 ǳǫ ȁŏ ǼŌȦ ɍ Ǜ°ÿ105 ǥǿǵ ǦǅǿǼ Ǩǯ ȷȁǫ ʔǿǵ Ƶȥ :**Loss on drying** ƵǅǫǿǼ ǼŌ

.ȟ/Ƞǫ

ƵǺŀş ŏţş R ȯǫǿǯŧ ǳǫ ǦşȆǫ ÿǫǅǵ ǳǫ ǰǫ Ž ȟ 0.5 ā ǿ :**4-Aminophenol** ȯǫǼǫǼǫ-4

ŏş ȖʓƩ ǕTS ɃǫŎ ÿǫǻǫȎ Ǽȅşşǿ ȯǫŢ ǳǫ Ōǫ 0.2 ȣ ȦȒ .ÆǿŧǰǫŢ ǿŏ Ōǫ 10 ʔǿǵ

-4 ǳǫ Ƀɿ R ȯǫǫȅǿǦ ǳǫ ȟ 0.5 ɃǫƷ ɄǅǫǦ ȯǫŢ ǦǫǕ ǦǕ ȀȒʒ .ǦǼǻ 30 ǥǼǫ ǿȅŸ

ȷǫȮ ɍ .¢ȆȦ ÆǿŧǰǫŢ Ž R ȯǫǼǫǼǫ -4 ȯǫŢ ǳǫ Ōǫ/Ƞǫ 0.050 ɃǫƷ ȯǫŢ ǳǫ Ōǫ 0.5ş ȯǫǼǫǼǫ

.(ȟ/Ƞǫ 0.05) ɄǅǫŧȯǫȢ ȷǫ ǳǫ Ǽȉ ǿǹɍ ȯǫŢ ȷǫ

ǦǼǻȍ ǦǕ āȊȅ" ȷǫʒ ǨƠ ȣǫȍǫ ǫȽ ȶŏ ǿǹɍ ȨǕ :**Related substances** ǦȊţ ǻǫţ

ǳǫ ȶǅǵ 65 ǳǫ ǰǫş Ǧ8ǫ ǥǻȶŏ R4 silica gel ȮŸȆ ǦǫŸȽ ÿǼǺȅ Ȗ"Thin-layer chromatography

Ǵȶ Ȇ .ŏǫ ǿǫȖŏ toluene R ǳǫǿǫȖ ȯǫŢ ǳǫ ÿǫǅǵ 10ş ȖR ȷǫȅɉ ǳǫ ȶǅǵ 25ş ȖR ÿǿǫşǿǫȮ

ǿǹɍ ŌǼŢ ȦȒȽ .ǦǕǫ Ƙȡ āȊȅ ǥǅǵ ȯȶȅ ȖȨǕ Ȕǹ ȧǫǫ ḻȅ 14 ǻǫȮ ÆǿŧǦȢ

ǥǻȅ Ƀ āǫǕ Ƀ ȎɍǫÆȥ ɄǿǦȶʒ ǦǫȆţ ǥǻţ ǳǫ ȟ 1.0 (A) ȯǫȢ ƘȒǿ ŌŌ :ǦǕ ǦǿɉŌȅ ʔʒ ȮȮȆȽ ʔǿǵ āǫɉ ŌȽ .ǦǼǻ 30 ǥǼǫ ʒş ȖR Ƙɉ ȯǫŢ ǳǫ Ōǫ 5 ȣ ȦȒ ȖǦǅǅȁ

Ōǫ 10 Ƀ A ȯǫȢ ǳǫ Ōǫ 1 ƵƩ (B) ȯǫȢ ƘȒǿ .ǦǫȮ ǥǻţ ǳʒ ȮȮş ȣȍ supernatant ȣù

750~) ỏɀɸİǯſɋǟ Ž R ǼŀŸŀɸİǪŀèǟşǿɀŸõ-4 ȸ ŊŸ 25 (C) ỏɀŸǂǟ ƘȒȞǪǒ ǟǟǾł .TS (ỏ/ȟ 750~) ỏɀɸİǯſɋİǣ Ž İȚÔȞɀ ǼƵ ȣøǪǒǟ ǵǻţǟ ȸ ȟ 0.1ş R ǼŀŸŀɸİǪŀèǟşǿɀŸõ-4 ȸ ȟ 0.25 (D) ỏɀŸǂǟ ƘȒȞǪǒ ǟǟǾł .TS (ỏ/ȟ ȸ ȀǪǒşȀỎŊ 200 ǦȞŀȀÔǒǟ ȝŸȝ ŀŸÔȀȀŊ ĘǤÛł .ǑŊ 100 ȝŸȝ ỏɀÔȞŸǒ TS (ỏ/ȟ 750~) ỏɀɸİǯſɋǟ ȸ ǦŀɀİȭǦŀŧõ Ž ƵǱɀǪǒ ȭȀǪǩ Ûǟǟ ȀȊǪèɍǟ ǵȀǱɀǵ ȸ ǦȞŀȀÔǒǟ ţȀɸ ǼȞǣ .ǦŀęȀǦǒǟ ǦǪŸǯǒǟ ǑŀǒȀǂǟ ȸ Ǒõ ȸ ȀǪǒşȀỎŊ 40ş A ỏɀŸǂǟ ǦƤİɸ ǦȞǑǣ ǦȀǕ ȷɀỎǩ ɍ .(ȀǪŊɀɸİɸ 254) ǦŀǱÊȀȀǦǒǟ ȧɀɀ ǦȞȉȷǟ ǒɀȒǣ ȣøǟǟȀȊǪèɍǟ ȖÛǺţǟ ȎȞȀſş ȕɀǟǻ ǒǟɀȽ ǿİŀǩ .C ỏɀŸǂİǣ İȚŀŸȝ ǑÔȞǪÊȀ ȣøǪǒǟ ǦǑǟȀÛţǟ ǦȞǑǦǒǟ ȸ ǵǼȉ ȀǯõȔ ÛA ỏɀŸǂİǣ İȚŀŸȝ ǑÔȞǪÊȀ ǼŀŸŀɸİǪŀèǟşǿɀŸõ –4 ȸȝ ȀǯõȔ ÛǼŀŸŀɸİǪŀèǟşǿɀŸõ –4 øǒ ǦǑǟȀÛţǟ ǦȞǑǦǒǟş ǦŀÊŀǝȀǒǟ ǦȞǑǦǒǟ ǒȀȀǯǪèİǣ ÛB ỏɀŸǂİǣ İȚŀŸȝ ǑÔȞǪÊȀ ǦȞǑǣ ǦȀǕ ȷɀỎǩ ɍ D ỏɀŸǂǟ ȸ ǰǨȀȀǒǟ ǟǟȀȊǪèɍǟ ȖÛȖ ȀȚşȔ ǟǣȔ ɍȔ ǺęşǼÔŊ ǿİǦǪǹɍǟ ȷɀỎȀ ɍ .C ỏɀŸǂİǣ ǦŸÔȞǪÊţǟ ǦǨǑǦǒǟ ȸ ǵǼȉ ǦȞǑǦǒǟ Ž ȒȀǹȔ R$_f$ ǦŧŀĘ ȷɀỎǩş ÛǦǒɀȞȀţǟ ǵǻţǟş ǼŀŸŀɸİǪŀèǟşǿɀŸõ-4 ƂȔ ȷǟƘȊǩ ƙǨȀȀŧǪŊ ƙǪǒɀÔȀŊ ƙǪȞǑǣ .ǵƘǹȷǟ

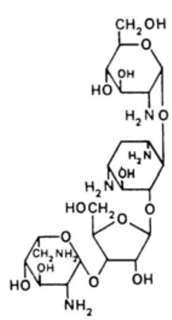
ǑȀǿɀŸõşǿǼŀŢǟ Ȓƥ ȸ ǑŊ 10 ȣİȒȀ ÛǦŸǱɀǵ ƂȔ ÛǦŀȕɀǦȒŊ ǦɸşȁɀŊ Ûȟ 0.25 ǦǣǟȀę ǑǑȀ :**Assay** ǦÊȀİǑţǟ ȣİȒȀ ÛǒȀţǟ ȸ ǑŊ 30 øǣ ƵǯỎţǟ ǑÊȣȀ .ǦȝİèǵǼŊ ȣȝɀǱȀǒǟ ȷȀȀƨİǣ ǑŧȞȀ ƵǯỎɨ ǨƠ ȝŀȣȀş TS (ỏ/ȟ 70~) ȷǟɀȀȞǒǟ ǨƠ ȣɀǒɀŊ ɀȽ İŊ ǼÊƜ ȝŧİǪłş Ûcombined solution Ǽǵɀţǟ ỏɀŸǂǟ ƂȔ R ȳɀŀèİǩɀǦǒǟ ǼŀŊşȀǣ ȸ ȟ1 ȕɀİỎȀ .VS (ỏ/ỏɀŊ 0.1) ȳɀȀǻɀÔǒǟ ǨȀȀǪȀǣ ǵȀȀȞţǟ Û(143 ǦȞȀÔǒǟ Û1 ǼŸǑǟ) "Nitrite titration ǨȀȀǪȀǒǟ ǵȀȀȞŊ" .$C_8H_9NO_2$ ȸ ŊŸ 15.12 VS (ỏ/ỏɀŊ 0.1) ȳɀȀǻɀÔǒǟ ǨȀȀǪɸ ȸ ȀǪǒ ȣŸŊ Ǒõ

PAROMOMYCINI SULFAS

Paromomycin sulfate ǱǏȝȊǱǨǱǨƥƑǦǁǁ ȴƑƻǂȝ

$C_{23}H_{45}N_5O_{14},xH_2SO_4$:**Molecular formula** ǦŀȀȀȝǟ ǦȣŀÔǒǟ

:**Graphic formula** ǦŀɸİŀǦţǟ ǦȣŀÔǒǟ



Chemical name [illegible]:

O-2,6-Diamino-2,6-dideoxy-β-L-idopyranosyl-(1→3)-*O*-β-D-ribofuranosyl-(1→5)-*O*-[2-amino-2-deoxy-α-D-glucopyranosyl-(1→4)]-2-deoxy-streptamine sulfate (salt); *O*-2-amino-2-deoxy-α-D-glucopyranosyl-(1→4)-*O*-[*O*-2,6-diamino-2,6-dideoxy-β-L-idopyranosyl-(1→3)-β-D-ribofuranosyl-(1→5)]-2-deoxy-D-streptamine sulfate (salt); CAS Reg. No. 1263-89-4.

Description [illegible]:

Solubility [illegible] (~750 [illegible]) TS [illegible] R [illegible]

Category [illegible]:

Storage [illegible]:

Additional information [illegible]:

REQUIREMENTS [illegible]

General requirement [illegible] 675 [illegible]

Identity tests [illegible]:

A: [illegible] "Thin-layer chromatography" (84 [illegible] 1 [illegible]) R3 [illegible] (40 [illegible]) [illegible] TS [illegible] 1 [illegible] (A) 20 [illegible] (B) 20 [illegible] RS [illegible] 105 °[illegible] 10 [illegible] 105 °[illegible] 5 [illegible] TS (triketohydrindene /butanol) [illegible] A [illegible] B [illegible]

B: [illegible] 0.05 [illegible] A [illegible] "General identification tests" [illegible] (123 [illegible] 1 [illegible]).

Бٳ ţ ƺǄÀőǺ ÆÊƷ ş Ōɳ/ɳŸɳ 50 ÂƗõÀQ ȯƺŸƮ ÿÆÁQÊʌ :**Specific optical rotation** Ʉʒƺ Bǹ ÀÔ Ǻ ş ÆQ

. $[a]_D^{20°C}$ = + 50 to +55° ÜǦÀÀÖ ğǻţ

.ȟ/ɳŸɳ20 ȸɳ Àǯõٳ È :**Sulfated ash** ǨÁŸÊţ ǻɳÀ

ɍ) ȐÀÁɳ Ȕ8 ȑ ǨƠ °ÿ50 ğøÀǵ ǄƺøÆ Ǩǯ ȷàƺ ʔøǵ Ƶǻƶ :**Loss on drying** ƵÀǄQǺ ÆÕÀ

.ȟ/ɳŸɳ 50 ȸɳ Àǯõٳ ÆÕÀ ɍ Ü(ÀÖ ɄÕ ɭŸɳ 5 şٳ ȯÀÒèƺÕ 0.6 àşǄQ

.7.5 – 5 ÛR ȷƺÀÒ ÆÊõٳ ɄÀQ ȸɳ ȯÀǹ ǒÀɳ Ž Ōɳ/ɳŸɳ 30 ÂƗõÀQ ȯƺŸƮ ǒÀŁÀ :**pH Value** ǒÀŁÀ Ǧȶ ę

ǦƺƩ ğǻÀȐȶ Ǆƺƺ şÀÒţ ǦÊÀÕţ" ȷƺʒ ǨƠ ȣƺǒƺɳ ƺŁ Àɳ ÆÊɯ ǦÊÀÕţ ĘǦÛ :**Assay** ǦÊÀÕţ

Bacillus ǦÕ ę ÀǦƺÔȞ (*a*) Àɳٳ ÿÆÁQèÀ Û(155 ǦȞÀÔ Û1 ÆŸÖ) "Microbiological assay of antibiotics

ǦøǻÛ8.0 ɄÀŒ (pH) ǒÀŁÀ ʒɳ Cml ǨQÊɳ Ûtest organism øÀQǹɍ Ʉǵ ȸÀÒõ (NCTC 10400) *subtilis*

37 ȸȒǵ ğøÀǵ ş Û(ğǻʒ Ōɳ/IU 4ş 1 ƙ) ƙÊɳƺɳşøÀ ȸɳ ÆèÀɳ ÂƗõÀ ÛTS Û7.8 ǒÀŁÀ ğ Ǧȶ Õʒ ğÀÊƺ

ǨQÊɳ Ûtest organism øÀQǹɍ Ʉǵ ȸÀÒõ (ATCC 6633) *Bacillus subtilis* ǦÕ ę ÀǦƺÔȞ (*b*) şٳ Ü°ÿ39 –

ƙÊɳƺɳşøÀ ȸɳ ÆèÀɳ ÂƗõÀ ÛTS2 şٳ TS1 Û8.0 ǒÀŁÀ ğ Ǧȶ Õʒ ğÀÊƺ Ǧøǻ Û7.8 ɄÀŒ ǒÀŁÀ ʒɳ Cml

fiducial ğÆȶ QȞţ ǻşÆƩ ÀƬƺ ȷƺÒ ɍ ȷٳ ɄŁ ǦÊÀÕţ Ǧę .°ÿ38 – 36 ȸȒǵ ğøÀǵ ş Û(ğǻʒ Ōɳ/IU 8ş 2 ƙ)

ǦŸʒÀÀ ȸɳ %105 ȸɳ Àǯõٳ ɍş %95 ȸɳ Ōęٳ (*P* = 0.95) estimated potency ğøÆÕţ ǦŸʒÀŸ üÛÁŸ limits

ÛɳŸɳ/ƙÊɳƺɳşøÀ ȸɳ IU 675 ȸɳ Ōęٳ (*P* = 0.95) ğøÆÕţ ǦŸʒÀŸ ÆȶQȞţ üÛÁŸ ɃƺŸȞ ÆƩ ȷƺÒ ɍ .ğøÆÕţ

.ǦÀÀÖ ğǻţ Бٳ ţ ƺǄÀőǺ ǦƺÊƮ

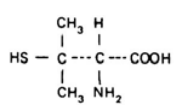
PENICILLAMINUM

Penicillamine ǄƺǄǗĩ ƨǦ

$C_5H_{11}NO_2S$:**Molecular formula** ǦÀÂƨ Ǧ8Ô

149.2 :**Relative molecular mass** ǦÊÀ ǦÀÂƨ ǦŸQÒ

:**Graphic formula** ǦÀǦţ Ǧ8Ô



:**Chemical name** ɄÀȶÒ ɭèɍ

3-Mercapto-D-valine; 3,3-dimethyl-D-cysteine; CAS Reg. No. 52-67-5.

Description [illegible].

Solubility [illegible] 9 [illegible] (1/750~) TS [illegible].

Category [illegible] antidote.

Storage [illegible].

Additional information [illegible].

REQUIREMENTS [illegible]

General requirement [illegible] 95% [illegible] 100.5% [illegible] $C_5H_{11}NO_2S$ [illegible].

Identity testes [illegible]:

A: [illegible] 20 [illegible] 4 [illegible] 2 [illegible] TS [illegible].

B: [illegible] 20 [illegible] 5 [illegible] 0.05 [illegible] (1/200~) TS [illegible] 20 [illegible] R [illegible].

Specific optical rotation [illegible] 50 [illegible] (1/1) VS [illegible] $[a]_D^{20°C}$ = - 58 to - 68°.

Sulfated ash [illegible] 1 [illegible].

Loss on drying [illegible] 60° [illegible] 0.6 [illegible] 5 [illegible] 5 [illegible].

pH Value [illegible] 10 [illegible] 4.0 – 6.0.

Mercury [illegible]:

[illegible].

[illegible] 0.5 [illegible] 650 [illegible]

[illegible]

[illegible]

[illegible] **Assay** [illegible] $C_5H_{11}NO_2S$ [illegible]

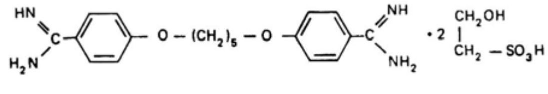
PENTAMIDINI ISETIONAS

Pentamidine isetionate [illegible]

$C_{19}H_{24}N_4O_2,2C_2H_6O_4S$ **:Molecular formula** [illegible]

592.7 **:Relative molecular mass** [illegible]

:Graphic formula [illegible]



[illegible] :**Chemical name**

4,4′-(Pentamethylenedioxy)dibenzamidine bis(2-hydroxyethanesulfonate); 4,4′-[1,5-pentanediylbis(oxy)]bis[benzenecarboximidamide]-bis(2-hydroxyethanesulfonate); CAS Reg. No. 140-64-7.

[illegible] :**Description** [illegible]

[illegible] :**Solubility** [illegible] 10 [illegible] (~750 [illegible]) TS [illegible] R [illegible] R.

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

[illegible] :**Additional information** [illegible]

REQUIREMENTS [illegible]

[illegible] :**General requirement** [illegible] 98.5% [illegible] 102.5% [illegible] $C_{19}H_{24}N_4O_2,2C_2H_6O_4S$ [illegible].

[illegible] :**Identification tests**

A: [illegible] 10 [illegible] (0.01 [illegible]) VS [illegible] 230 [illegible] 350 [illegible] 262 [illegible] 1 [illegible] 0.47 [illegible].

B: [illegible] 0.5 [illegible] 5 [illegible] 80 [illegible] 10 [illegible] (~50 [illegible]) TS [illegible] 2 [illegible] 0.2 [illegible] (~1000 [illegible]) TS [illegible] 0.2 [illegible] ceric TS [illegible].

C: [illegible] 190 [illegible].

[illegible] :**Sulfated ash** [illegible] 1.0 [illegible].

[illegible] :**Loss on drying** [illegible] 105 [illegible] 40 [illegible].

[illegible] :**pH Value** [illegible] 0.05 [illegible] 4.5 – 6.5.

[illegible] :**Related substances** [illegible]

ǦDZǿǼǣ ǦŸǶǺŋ ÛR6 silica gel ǺÒǼŸǼÊǿǟ ǦŋƳŁ ǉǟǼǺǪèǺǣ Û(84 ǦǶǺÔǿǟ Û1 ǼŸÕǟ) Û"Thin-layer chromatography ƾŸȝ ǾÔǶǪÊǺ ōǺǶǪŋ ǿǭÛōş Û(ǦŧǝƳŋ ɃǿǺƟ ǿǼÔŋ ȸŋ ǦŸǿ8ţǟ ǦǶǼǺÔǿǟ) ǦŸǿ8ŋ ǥǺǺŧō ÛǦȝǺè ǥǼŋ °ÿ 105 ǥǿǟǺǵ
.ǦǶŧǪƒ R ɄDZŸǯǿǟ ŌǼǪèɉǟ Ȁþ ȸŋ ƙŧDZǵş ÛR ȯǭǪǺǩǭǣ -1 ȸŋ ǉǭDZǵ 8 ÛǿǺŋ ǉǭDZǵ 10 ǯǺǣ ǼŸǶǿǟ ǦǾǦÛǿǟ
Ž ǿǺǪǹɍǟ ǥǺǺŋ ȸŋ ŊŸŋ 50 ƾŸȝ ɃǭǪȜ (A) :R ȯǭǪǺǯǼţǟ Ž ƙȯǭŸƬ ȸŋ ǺǪǿşǺÒŋ 10 ǦǶǼǺÔǿǟ ƾŸȝ ŸÔǺǺŋ ĘǦÛƚ
Ž ȤDZǪǿ ōǺǪǩ ÛāǟǺÎǪèɍǟ ǥǺDZǵ ȸŋ ǦǶǼǺÔǿǟ ţÂǪ ǼǶǣ .ǺǪǿ ɄŸǼţǟ Ž ǿǺǪǹɍǟ ǥǺǺŋ ȸŋ ŊŸŋ 0.25 (B)ş ǺǪǿ ɄŸǼţǟ
ÛA ȯǭŸǂǟ ȸŋ ǰǪǩ ǦǶŌǣ ǦǺÛ ȷǭÒǩ ɍ .(ǺǪŋǭǪǺǪ 254) ǦǼDZÊǺǦǿǟ ȧǭǭ ǦǶȉɉǺǣ āǟǺÎǪèɍǟ ÙÛƯ ÒǶǺǪş ÛǿǟǭŢǟ
.B ȯǭŸǂǟ ȸŋ ǦƟǺǿǟ ŌŸǩ ȸŋ ǥǼȉ ǺǯōǺ ÛǦǼÊǼǝǺǿǟ ǦǶŌǦǿǟ ǿǺǯǪèǺǣ

Determination of ƙDZşǺǪǺǿǟ ƙǼǶǩ" ȷǟǭǺȝ ǨƠ ȣǭȍǭŋ ǭŁ Ǻŋ ǢÊɆ A ǦŌǺǺÛǿǟ ĘǦÛǩ :**Assay** ǦÊǺǺŌţǟ

Ȁþ ȸŋ Ōŋ 9ş ÛǦǼùǭǦȒŋ ǦǪşǟǭŋ ÛǶǦǺǺŌǩ ǿǺǪǹɍǟ ǥǺǺŋ ȸŋ ȟ 0.4 ǉǟǼǺǪèǺǣ Û(147 ǦǶǺÔǿǟ Û1 ǼŸÕǟ) "nitrogen

ùǭǺÒǺ VS (ȯ/ȯǭŋ 0.05) ŌǺǿǭǺŸÊǿǟ Ȁþ ȸŋ Ōŋ 1 Ōō .TS (ȯ/ȟ 1760~) ƙDZşǺǪǺǿǟ ȸŋ ƃǺƪǟ ŌǺǿǭǺŸÊǿǟ

.$C_{19}H_{24}N_4O_2,2C_2H_6O_4S$ ȸŋ ŊŸŋ 14.82

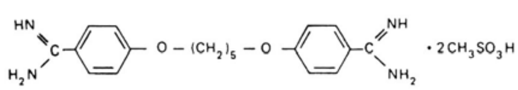
PENTAMIDINI MESILAS

Pentamidine mesilate DZǏǪǏDZǰǶǼǦǇǀ ǀűǏƨǏDZ

$C_{19}H_{24}N_4O_2,2CH_4O_3S$:**Molecular formula** ǦǼǺǺÂƨǟ ǦǾǼÔǿǟ

532.6 :**Relative molecular mass** ǦǼǦÊǺǿǟ ǦǼǺǺÂƨǟ ǦŸǪÒǿǟ

:**Graphic formula** ǦǼǪǺǼǦţǟ ǦǾǼÔǿǟ



:**Chemical name** ɄǝǺǼŧǼÒǿǟ ǀèɍǟ

4,4′-(Pentamethylenedioxy)dibenzamidine dimethanesulfonate; 4,4′-[1,5-pentanediylbis(oxy)]bis[benzenecarboxamidamide] dimethanesulfonate; CAS Reg. No. 6823-79-6.

.ǺǦǺǺŌǩ ǦǶǝǺǺǿǟ ƇǼȝ ÜɄǿǼǦǵ ÛǨŁǺǣ ɄŸǺǪǺę şǺ ȀǼǺÛ ȷǭŸǣ ȧǭǶÊŋ :**Description** ȤȍǭǿǞ

ÛR ȷǭǪǼèɉǟş ÛR ƘǫɉǟŽ āǟşǼ ɍ ÜTS (ȯ/ȟ 750~) ȯǭǪǺǯǺǪǟş ǿǺţǟ Ž ȷǺǣşǾǿǟ ǴǼǶȉ :**Solubility** ǦǼǪǺǣşǾǿǟ

.ǺǼŸŧȝ R ǉǿǭǭşǿǭŸÒǿǟ Ž ɍş

.ğ ÀŁǫÀȶ ÎŀŸöä åÀR̂ɳ Ü ğ ÀŁǤÕǯţä åÀR̂ɳ :**Category** ǦÀÀöä

.ÀÆŀDZ ǦÕŸ8ɳ ǦÀşÀǵ Ž ȸÀÆŀɳÀǪÀǦöä ğ ŸŀÊŀɳ ŞÀĦł ɹÜ Æƶ :**Storage** ȸÀÂÁǪöä

RQUIREMENTS ƘǦhǘƱkdž!ƒ

ȸʒ ÆÀÂÀ ɏş %98.5 ȸʒ ÕÕÀ ɏ Àɳ ʔŸʒ ȸÀÆŀɳÀǪÀǦöä ğ ŸŀÊŀɳ Ƀɀǫʒ :**General requirements** ÿÀĤöä ÆŸÛǪţä

.ǦÀÀÕä gåÀţä ƂÜ ţɀDZÀöÀæ ǦæɀÊƮ Û$C_{19}H_{24}N_4O_2,2CH_4O_3S$ ȸɳ %102.5

:**Identity tests** ƕǏNjNJǁɛ ƖɛƥƑǶƢɛ

ÆŀÊõşøÆŀŁ ȸɳ Õɳ 10 ȣÀR̂À .ā şØŀö °ÿ80 gøäÀΣä ǦDZøå ƂÜ ȸÁÊÀş ŏÀɳ Õɳ 5 ȟ 0.5 ƂÜ ȣÀR̂À :A

ÕÀÀǪÀöä R̀ ƥ ȸɳ Õɳ 0.2 Ǧǵ ÀïÀöä ȸɳ Õɳ 2 ƂÜ ȣÀR̂À .ǴǹïÀÀş ÛÆŀŸƨä Ž åƎÀ ÛTS (ȯ/ȟ 50~) ÿɀÀåɀÔöä

.ÀÀòÜ ɹɀö ǰǪÀÀ ÜTS ceric ÕÀƘÊöä ÿɀŀǫɀɳÜ ğ äÀǪǫ ȸɳ Õɳ 0.2 øæ ʒǦǪÀ TS (ȯ/ȟ 1000~)

õøÆǩ ÛÀŀǫɀɳɟä ǰǪÀǩ ÜøÀǦǪǹä āɀǦǫÜ Ž TS (ȯ/ȟ 400~) ÿɀÀåɀÔöä ÆŀÊõşøÆŀŁ ȸɳ Õɳ 1 ʒɳ ȟ 0.5 ȸÁÊÀ :B

.ÀƬǪĦəäÀæ

ÛTS (ȯ/ȟ 50~) ÿɀÀåɀÔöä ÆŀÊõşøÆŀŁ ȸɳ Õɳ 10 ȣÀR̂À Û°ÿ80 gøäÀǵ ǦDZøÆæ ŏÀɳ Õɳ 10 Ž ȟ 1 āäØÀ :C

Ü°ÿ105 gøäÀǵ ǦDZøÆæ ǦæÀèÀöä ȤÀΘş ÛŏÀɳ Õɳ 10 øæ ÕÊ8À Û(D øÀǦǪǹŸö Ǧǵ ÀïÀöä ŞÀƠ) ǴǹïÀÀ ÛÆŀŸƨä Ž åƎÀ

.ÀǦÀÕǩ °ÿ188 ÛøÀƬÔǫɏä ǦDZøå

60~) ƙDZşøÆŀƮä ÆŀÊõşƘæ Õɳ 2.5 ȣÀR̂À ÛǦŀÆŀǩŸæ ǦÕǩɀæ ƂÜ C øÀǦǪǹɏä ȸɳ ǦΘÀÀöä Ǧǵ ÀïÀöä ȸɳ Õɳ10 ÕÕÀÀ :D

R̀ ƥ Õɳ 1 ȣÀR̂À ÛŏÀɳ Õɳ 1 Ž ɄɇÀǦöä āäØÀ .ɄəÀɳ ÿÀƥ Ž ȣÀÀƨä ʔøǫǵ ÀÁǦÀş ɄDZÀDZä åɀĦæ ʓÂɀ ÛTS (ȯ/ȟ

ȸɳ ÀŀöÀǹ ǴǦÔÀ ʔøǫǵ (ÆɳÀÀ) ÕĤÎł Ż ÛɄəÀɳ ÿÀƥ Ž ȣÀÀƨä ʔøǫǵ ʡÀǹÜ gÀɳ ÀÁǦÀş R ɄDZŸǯöä ÕŀǪŀèɟä

70~) ÕÀøɀŸõşøÆŀƮä R̀ȶɯ ȯÆŀĤǪÊÀ .ÀÀøşÀȓ Õöæ ɹÀõ äæÜ ÛǴïÀÀş ŏÀɳ Õɳ 5 Ž ɄɇÀǦöä ʓÂɀ ÛåƎÀ .ɹɀæÀÒöä

ğ äøÀǦǪǹä" ɹäɀʒ ǨƠ ȣɀòɀţä A ÕʒÀÀǪöä ʒæÀǪÀş åƎÀ ÛǦŀǫÀǫ 30 gÆɳ ʔǹ8À .Õɳ 3 ÀÆÀä ȣÀR̂Àş TS (ȯ/ȟ

.(123 ǦĦÀÔöä Û1 ÆŸÕä) ğ ÀÀŸÊŸö Àŀȶȶõ "General identification tests ǦɳÀĤöä ȣäÀĤǪèɏä

.ȟ/ɳŸɳ 1.0 ȸɳ ÀǯõÜ Èŀö :**Sulfated ash** ǨÀŸÊţä åÀɳÀöä

15 ȸɳ ÀǯõÜ ÆÕÀÀ ɏ Ü°ÿ105 gøäÀǵ ǦDZøÆæ ǨæÀǯöä ɹàɀöä ʔøǫǵ ȤÀƶ :**Loss on drying** ȤŀÀDZǫÕÀæ ÆÕÀöä

.ȟ/ɳŸɳ

.6.5 – 4.5 ÜåƎÀ Ż ùɀäå ŏÀɳ Ž Õɳ/ȟ 0.05 ÀŀõÀǪæ ȯɀŸƮ ŏÀŁÀæ :**pH Value** ŏÀŁÀǦöä Ǧȶŀȩ

ǦÕŀȩÀöä ǦÕǦÛöä āäÀÎǪèä" ɹäɀʒ ǨƠ ȣɀòɀɳ ɀŁ Àȶõ øÀǦǪǹɏä ȨǦÛÀ :**Related substances** ǦöÀÎţä åäɀţä

[illegible] R6 silica gel [illegible] (84 [illegible] 1 [illegible]) "Thin-layer chromatography [illegible] 105 [illegible] R [illegible] -1 [illegible] 8 [illegible] 10 [illegible] 50 [illegible] (A) [illegible] R [illegible] 10 [illegible] 0.25 (B) [illegible] 254) [illegible] B [illegible] A [illegible].

Determination of [illegible] A [illegible] **Assay** [illegible] 9 [illegible] 0.4 [illegible] (147 [illegible] 1 [illegible]) "nitrogen [illegible] VS (0.05) [illegible] 1 [illegible] TS (1760~) [illegible] 13.32 [illegible] $C_{19}H_{24}N_4O_2,2CH_4O_3S$.

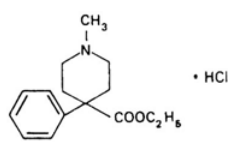
PETHIDINI HYDROCHLORIDUM

Pethidine hydrochloride [illegible]

$C_{15}H_{21}NO_2,HCl$:**Molecular formula** [illegible]

283.8 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

Ethyl 1-methyl-4-phenylisonipecotate hydrochloride; ethyl 1-methyl-4-phenyl-4-piperidinecarboxylate hydrochloride; CAS Reg. No. 50-13-5.

[illegible] :**Other name** [illegible]

[illegible] :**Description** [illegible]

[illegible] R [illegible] TS (750~) [illegible] :**Solubility** [illegible]

[illegible] **Category**: [illegible].

[illegible] **Storage**: [illegible].

[illegible] **Additional information**: [illegible].

REQUIREMENTS [illegible]

[illegible] **General requirement**: [illegible] %98.0 [illegible] %101.0 [illegible] $C_{15}H_{21}NO_2,HCl$ [illegible].

Identity tests: [illegible]

A: [illegible] 5 [illegible] 0.5 [illegible] 0.1 [illegible] 2 [illegible] (~1760 [illegible]) [illegible].

B: [illegible] 0.1 [illegible] 5 [illegible] (~750 [illegible]) [illegible] 15 [illegible] (7 [illegible]) [illegible] 105° [illegible] (picrate [illegible]) 190° [illegible] (C [illegible]).

C: [illegible] 5 [illegible] 5 [illegible] B [illegible] 20° [illegible].

D: [illegible] 10 [illegible] A [illegible] General identification tests" [illegible] (121 [illegible] 1 [illegible]).

[illegible] **Melting range**: [illegible] 105° [illegible] 187 – 190°.

Clarity and colour of solution: [illegible] 0.20 [illegible] 10 [illegible].

Sulfated ash: [illegible] 1.0 [illegible].

Loss on drying: [illegible] 105° [illegible] 5.0 [illegible].

pH Value: [illegible] 0.05 [illegible] 4 – 6.

Related substances: [illegible]

[illegible] R1 [illegible] (84 [illegible] 1 [illegible]) "Thin-layer chromatography [illegible] 5 [illegible] R [illegible] -2 [illegible] 9 R [illegible] 15 [illegible] R [illegible] -2 [illegible] 8 R1 [illegible] 100 R [illegible] 0.5 [illegible] 5 [illegible] 0.10 [illegible] 2 TS (400~) [illegible] B [illegible] 50 [illegible] A [illegible] 0.5 [illegible] A [illegible] B [illegible] A [illegible] 5 [illegible] 12 [illegible] 10 [illegible] 5 [illegible] TS [illegible] 10 [illegible] A [illegible] (365) [illegible] B [illegible].

10 [illegible] R1 [illegible] 30 [illegible] 0.20 [illegible] :**Assay** [illegible] VS (0.1) [illegible] TS [illegible] 1 [illegible] (142 [illegible] 1 [illegible]) A [illegible] "Non-aqueous titration [illegible]" [illegible] $C_{15}H_{21}NO_2$,HCl [illegible] 28.38 [illegible] VS (0.1) [illegible].

[illegible]

Additional requierments for Pethidine hydrochloride for parenteral use

(56 [illegible] 4 [illegible]) "*Parenteral preparations* [illegible]"

[illegible] :**Bacterial endotoxins** [illegible] (30 [illegible] 5 [illegible]) "Test for Bacterial endotoxins [illegible] 2.4 RS [illegible].

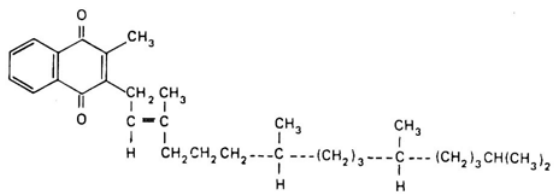
PHYTOMENADIONUM

Phytomenadione [illegible]

$C_{31}H_{46}O_2$:**Molecular formula** [illegible]

450.7 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

Phylloquinone; [*R*-[*R**,*R**-(*E*)]]-2-methyl-3-(3,7,11,15-tetramethyl-2-hexadecenyl)-1,4-naphthalenedione; 2-methyl-3-phytyl-1,4-naphthoquinone; CAS Reg. No. 84-80-0.

.K_1 [illegible] Phytonadione [illegible] :**Other name** [illegible]

.[illegible] :**Description** [illegible]

[illegible] TS (750~ [illegible]) [illegible] :**Miscibility** [illegible]

.R [illegible] R [illegible]

.[illegible] :**Category** [illegible]

.[illegible] :**Storage** [illegible]

RQUIREMENTS [illegible]

102.0 [illegible] %97.0 [illegible] :**General requirements** [illegible]

.$C_{31}H_{46}O_2$ [illegible]

:**Identity tests** [illegible]

[illegible] R [illegible] -4[illegible]2[illegible]2 [illegible] 10 [illegible] :A

261[illegible] 249[illegible] 243 [illegible] 4 [illegible] 350[illegible] 230 [illegible]

0.42 0.40 1 270 266 254 246 0.39 0.38 0.70 249 254 0.75

0.10 243 350 230 0.22 0.70 1 285 1.0 (750~) 5 0.05 15 TS1

$n_D^{20} = 1.525 - 1.529$ **Refractive index**

20 1 **Acidity or alkalinity**

Related substances "Thin-layer chromatography" silica gel R4 (84) 20 80 10 0.05 (B) 5 (A) (254)

Assay

0.1 100 100 10 100 10 249 1 $C_{31}H_{46}O_2$ 42 $\left(A_{1cm}^{1\%} = 420\right)$

[illegible]

Additional requierments for Phytomenadione for parenteral use

.(56 [illegible] 4 [illegible]) "*Parenteral preparations* [illegible]" [illegible]

[illegible] :**Bacterial endotoxins** [illegible] (30 [illegible] 5 [illegible]) "Test for Bacterial endotoxins [illegible] 14 RS [illegible].

PIX LITHANTHRACIS

Coal tar [illegible]

[illegible] :**Composition** [illegible] CAS Reg. No. 8007-45-2.

[illegible] :**Description** [illegible]

[illegible] :**Solubility** [illegible] (750~ [illegible]) [illegible] .R [illegible] R [illegible] R [illegible] TS

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

[illegible] :**Additional information** [illegible] sooty [illegible]

REQUIREMENTS [illegible]

:**Identity test** [illegible]

[illegible] 0.5 [illegible] 10 [illegible] R1 [illegible] 30 [illegible] (365 [illegible]).

[illegible] :**Sulfated ash** [illegible] 20 [illegible].

PRAZIQUANTELUM

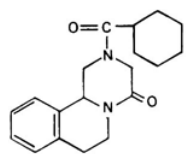
Praziquantel [illegible]

[illegible] 9 [illegible]

$C_{19}H_{24}N_2O_2$:**Molecular formula** [illegible]

312.4 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

2-(Cyclohexylcarbonyl)-1,2,3,6,7,11b-hexahydro-4*H*-pyrazino-[2,1-*a*]isoquinolin-4-one; CAS Reg. No. 55268-74-1.

[illegible] :**Description** [illegible]

.R [illegible] TS (~750) [illegible] :**Solubility** [illegible]

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

REQUIREMENTS [illegible]

[illegible] %101 [illegible] %98.5 [illegible] :**General requirement** [illegible]
[illegible] $C_{19}H_{24}N_2O_2$

:**Identity tests** [illegible]

- C [illegible] B [illegible] A [illegible]

A: [illegible] "Spectrophotometry in the infrared region" [illegible] (43 [illegible] 1 [illegible]) [illegible] RS [illegible]

B: [illegible] ."Related substances" [illegible] A [illegible] B.

.ǺǤǖǼǨ °ÿ138 ÛøǺƬÔǫɍǟ ǤDZøǻ :C

ȷǟǲǺȝ ǨƠ ȣǲòǲƞ ǲȽ Ǻȶõ ȟ 1.0 ǬȶȞǪÊǺ øǺǪǹɍǟ òǲŸȚ ƙȒƠ ȣǼõ :**Heavy metals** ǦŸǼǬǯõǟ ȷǻǺȞţǟ
Ü(127 ǤǶǺÔõǟ Û1 ǼŸǑǟ) 3 ǤǬǺǼÛõǟ ÆÊШ "Limit test for heavy metals ǦŸǼǬǯõǟ ȷǻǺȞţǟ ǬDZɉ ɃǼƩǟ øǺǪǹɍǟ"
.ȟ/ÿǟǺȡȘǼÒƞ 20 ȸƞ ǼǯõǛ ÈǼõ Ü(128 ǤǶǺÔõǟ Û1 ǼŸǑǟ) A ǤǬǺǼÛõǟ ÆÊШ ǦŸǼǬǯõǟ ȷǻǺȞţǟ ȸƞ ɁǲǪǂǟ ǻǼȜ

.ȟ/ƞŸƞ 1 ȸƞ ǼǯõǛ ÈǼõ :**Sulfated ash** ǨǺŸÊţǟ ǻǺƞǼõǟ

ÈǼõ) ȒǺǺǺƞ Ü8ȓ ǨƠ °ÿ50 ǥøǟǺǵ ǤDZøǼǟ ǨǟǯǼǟ ȷàǲõǟ ɁøǪǵ Ƶǻƶ :**Loss on drying** ƵǼǺDZǪǼǟ ǼǬǺõǟ
.ȟ/ƞŸƞ 5.0 ȸƞ ǼǯõǛ ǼǬǺǺ ɍ ÜƙǪȝǺè ǥǼƞ (ǺǤǺǼǨ ɄǬǤǝ ȴŸƞ 5 ȘǛ ȯǺǑèǺǟǲŸǼõ 0.6 ȸƞ ǼǯõǛ

ǤǬǤÛõǟ ǟǟǺÎǪèǟ" ȷǟǲǺȝ ǨƠ ȣǲòǲƞ ǲȽ Ǻȶõ øǺǪǹɍǟ ȨǤÛǺ :**Related substances** ǤǒǺÎţǟ ǻǟǲţǟ
ǥǻǺȶõ R5 silica gel ǺǑǼŸÊõǟ ǤƞȾȽ ÿǟǼǺǪèǺǟ Û(84 ǤǶǺÔõǟ Û1 ǼŸǑǟ) "Thin-layer chromatography ǤǬǼȩǼõǟ
.ǤǺÛǤƞ Ƙȡ ǥǼDZǵ ǬȶȞǪÊǨ .õǼǶǪƞ øǲÛõ R òǲǫǺǯǼţǟ ȸƞ ǺȶDZǵ 15Ș R ȸǺǲǒǲÛõǟ ȸƞ ǺȶDZǵ 85 ȸƞ ǰǺǺƞȘ ǦŸǼ8ƞ
50 (A) Ƀǲȝ :R ÿøǲǲȘøǲŸǑõǟ Ž ƙǒǲŸȚ ȸƞ ǼǪǒȘǼÒƞ 10 ÛR ƙDZȘǼǪǼõǟ ȸƞ øǺǼǨ Ž ÛǤǶǼǺÔõǟ ɁŸȝ ȾÔǺǺƞ ȨǤÛǺ
ȸƞ ǼǪǒȘǼÒƞ 2 ǺȒǺǛ ȨǤÛǺ ÜǼǪǒ ɄŸǼţǟ Ž RS ǬǼǪǫǟǲǑǺǟǟǝõǟ ȸƞ ƞŸƞ 50 (B)Ș ǼǪǒ ɄŸǼţǟ Ž øǺǪǹɍǟ ǥǻǺƞ ȸƞ ƞŸƞ
ǬǼǪǫǟǲǑǺǟǟǝõǟ ȸƞ ƞŸƞ 1.0 (D)Ș ǼǪǒ ɄŸǼţǟ Ž RS ǬǼǪǫǟǲǑǺǟǟǝõǟ ȸƞ ƞŸƞ 0.5 (C) Ƀǲȝ :R ÿøǲǲȘøǲŸǑõǟ Ž ƙǒǲŸȚ
Ž ƵDZǪǒ õǼǪǨ Ûǟǟ̀ǺÎǪèɍǟ ǥǼDZǵ ȸƞ ǤǶǼǺÔõǟ ţÂǫ ǼȞǟ .ȴè 7 ǻǲȞÔǺǟ õǼǶǪţǟ øǲÛŸǒ ǴȶÊǺ .ǼǪǒ ɄŸǼţǟ Ž RS
ÙÛǺţǟ ÒǶǺǺ .ǤǬǼȩǻ 20 ǥǼƞ ǼǬǪÊǪǒ õǼǪǨȘ ǻǲǼõǟ ǥǼȠǛ ȝƞ ǥǼDZǵ Ž ǤǶǼǺÔõǟ ȝȓǲǨ ÛùǲǟǺ ǒǟǲȽ øǺǼǨ
ǬŸǨ ȸƞ ǥǼì ǼǯõǛ ÛǤǼÊǼǝǼõǟ ǦȞǤǤõǟ ǒǺǺǯǪèǺǟ ÛA òǲŸǂǟ ȸƞ ǰǪǨ ǦȞǬǟ ǤǺǛ ȷǲǑǨ ɍ .øǺƬǺõǟ ǒǲȓ Ž Ǻøǲǲ ɄøǟǺÎǪèɍǟ
.D òǲŸǂǟ ȸƞ ǤƟǺǺõǟ ǬŸǨ ȸƞ ǥǼì ǼǯõǛ ȷǲǑǨ ɍ ɄøǪõǟ ǤǼèǺèɉǟ ǦȞǤǤõǟ ȧǲǲ ǦȞǬǟ ǟǼȝ Ǻƞ ÛC òǲŸǂǟ ȸƞ ǤƟǺǺõǟ

ǰǪǼõ (ò/ȟ 750~) R òǲǫǺǯǼţǟ ȸƞ ǤǼǲǺõ ǤǼȶõ Ž ÛǤǼùǲǤȒƞ ǤǫȘàǲƞ ÛƞŸƞ 0.04 ǤǟǟǺǫ ǟǟǿǺ :**Assay** ǤÊǺǬţǟ
$C_{19}H_{24}N_{2}O_{2}$ ǤǼȶõ ÆÊƠ .ǼǪƞǲǫǺǫ 265 ǤDZǲƞ òǲÛǟ ɄȶȚȝɉǟ ǤǼǵ Ž ȴè 1 ǤǫǺǺǯǟ ǤǬǤÛǒ ȋ ǺȶǪõǟ ǟǺǬǺ ÜǑƞ 100
.ȸƞǟǺǪǟȘ ǤǒǺÎţǺǟ ȋ ǲǶǺţǟ ÛRS ǬǼǪǫǟǲǑǺǟǟǝõǟ ȝƞ ǤǫøǺǬţǺǟ ǤòǲǶǺţǟ ǥǻǺţǟ Ž

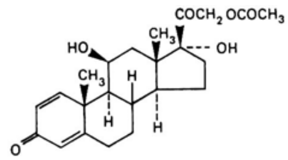
PREDNISOLONI ACETAS

Prednisolone acetate ǄǻǈǂǈǂȒǏǐǑǒǓ ǔǕǖǗ

$C_{23}H_{30}O_{6}$:**Molecular formula** ǤǼǺǺÂƨǟ Ǥ8ǼÔõǟ

402.5:**Relative molecular mass** ǤǼǤÊǺõǟ ǤǼǺǺÂƨǟ ǦŸǪǑõǟ

Graphic formula:



Chemical name:

11β,17,21-Trihydroxypregna-1,4-diene-3,20-dione 21-acetate; 21-(acetyloxy)-11β,17-dihydroxypregna-1,4-diene-3,20-dione; CAS Reg. No. 52-21-1.

Description:

Solubility: ~750 (ŏ/ȟ) TS ... R

Category:

Storage:

Additional information: 235 °ÿ

REQUIREMENTS

General requirement: 96.0% ... 104.0% $C_{23}H_{30}O_6$

Identity test:

- A ... B

A: "Spectrophotometry in the infrared region" (43 ... 1) ... RS

B: "Thin-layer chromatography" (84 ... 1) ... R1 ... 10 ... 5 ... R ... 90 R

ÆΛØţä ÀÅGΩΛ ʔøϘǵ ǴzÀ8öä gøäÀǵ Ž øäÀÕϘèŸö ÕÀϘķş āäÀÎϘèɍä gÀDzǵ ȸ ǦĦǁÀÔöä ţÂøÀǩ ÛÕϙɉä ʔŸȝ ȴè 16 ÕÀĦϘţä øzÛöä ÀŘȜ .ÀŐäæ ÆΛÀÎϘöä ǴȚDZ Ž āäÀÎϘèɍä öäÀDZüæ ÛƘϘȝÀè òŸǹ ǴæÀÎϘţä ǦĦǁÀÔöä ÿÆÅϘÊǩ .ŸȠÀÕ ȸ ÀϘöşÀÒȠ 2 ǦĦǁÀÔöä ʔŸȝ ŸÔÀȠ ĘǴÛΛ .R ÿøzzşøzŸÒöä ȸ ÀȶDzǵ 25ş R ȸΛzözÛöä ȸ ÀȶDzǵ 75 ÿäÆÅϘèÀæ gÅȠ ȸ ȠŸȠ 2.5 (A) ɃzȜ :R òzφÀǯţä ȸ Æǵäş ȴDzǵş R ÿøzzşøzŸÒöä ȸ ÿzDzǵ 9 ȸ ǰΛÂȠ Ž ƙözŸȚ ÆĦæ .ȴè 15 ǴzÀÊȠ ǦĦǁÀÔöä ÀȚȚł .Àϙö ɄŸȜţä Ž RS ɉzöşÂƎφåƎöä ğÀϘƎèǗ ȸ ȠŸȠ 2.5 (B)ş Àϙö ɄŸȜţä Ž øÀGΩǹɍä 15 gÆȠ °ÿ120 ǴDZøÆæ ȸÅÊǩ ÛÆΛØţä ÀÅGΩΛ ʔøϘǵ öäzȚä Ž ȤDzϘö ÕÀϘǩ ÛāäÀÎϘèɍä gÀDzǵ ȸ ǦĦǁÀÔöä ţÂφ ȸÅÊǩ Ż Û(ò/ȟ 750~) òzφÀǯΛqä ȸ ŌȠ 80ş TS (ò/ȟ 190~) ŌΛøzÀŸÊöä ȐƥȸŌȠ 20 ȸ ǰΛÂȠ æÀǩ ÛǦŌƎęå 365) ǴƎDzÊÀΛGöä ȧzz ǴĦìɉÀæş øÀȚΛöä özȑ Ž āäÀÎϘèɍä ÙÛƯ ÒĦÀΛş åƎϘö ÕÀϘǩ .ĘəÀęå 10 gÆȠ °ÿ120 ǴDZøÆæ

.B òzŸǂä ȸȝ ǦΘÀΛöä ŌŸǩ ȝȠ gÆÎöäş ÀȚȚţäş ȝęzţÀæ A òzŸǂä ȸ ǦΘÀΛöä ǴƎÊƎəÀöä ǦĦŌGöä ĘzäzϘǩ .(ÀϘȠzφÀφ

TS (ò/ȟ 700~) ŌΛøzÀŸÊöä ȐƥȸŌȠ 2ş TS (ò/ȟ 750~) òzφÀǯΛqä ȸ ŌȠ 2 ȟ 0.05 ɃǗ ȣÀŘΛ :C

.(øØШ ʔÀƶ) ¢ϘĦəäÀæ ÕøÆΛ ÛŌƎǯΛqä ğÀϘƎèǗ ǰΩΛΛ ÜgÆǵäş ǦŌƎęå gÆȠ ȤÛŸæ ʔŸ8Λş

ÜR ɉÀÊõzΛÆöä Ž ŌȠ/ȠŸȠ 10 ÂƎÕÀϘæ òzŸȚ ÿÆÅϘÊΛ :**Specific optical rotation** ɄȝzΛöäɃÀÔGöä ÀΛşÆϘöä

$.[a]_D^{20°C} = +112 \text{ to } +119°$

10 ȸ ÀǯŌǗ ÆŌÀΛ ɍ Ü°ÿ105 gøäÀǵ ǴDZøÆæ ƘæÀǯöä ɉàzöä ʔøϘǵ ȤÀƶ :**Loss on drying** ȤƎÀDzϘöÀæ ÆŌÀöä

.ȟ/ȠŸȠ

ǦŌƎęÀöä ǦŌGÛöä āäÀÎϘèä" ɉäzΛȝ ƘƠ ȣzòzȠ zȽ ÀȶŌ øÀGΩǹɍä ĘǴÛΛ :**Related substances** ǦŏÀÎţä åäzţä ǦŸȠ8Ƞ gÅȶŌ R1 silica gel ÀÒƎŸƎÊöä ǴȠŸȽ ÿäÆÅϘèÀæ Û(84 ǦĦÀÔöä Û1 ÆŸŎä) "Thin-layer chromatography .ÕÀĦϘȠ øzÛŌ öÀţä ȸ ȴDzǵ 0.2ş ÛR òzφÀǯƎţä ȸ ÿzDzǵ 5ş ÛR ɉÀǯΛǗ şøzŸŌ ɄəÀΛφ ȸ ÀȶDzǵ 95 ȸ ǰΛÂȠş ȸ Æǵäş ȴDzǵş R ÿøzzşøzŸÒöä ȸ ÿzDzǵ 9 ȸ ǰΛÂȠ Ž ƙözŸȚ ȸ ÀϘöşÀÒȠ 1 ǦĦǁÀÔöä ʔŸȝ ŸÔÀȠ ĘǴÛł ÆĦæ .Àϙö ɄŸȜţä Ž øÀGΩǹɍä gÅȠ ȸ ȠŸȠ 0.30 (B)ş Àϙö ɄŸȜţä Ž øÀGΩǹɍä gÅȠ ȸ ȠŸȠ 15 (A) ɃzȜ :R òzφÀǯƎţä 10 gÆȠ °ÿ 105 ǴDZøÆæ ȸÅÊǩ Ż ÛÆΛØţä ÀÅGΩΛ ʔøϘǵ öäzȚä Ž ȤDzϘö ÕÀϘǩ ÛāäÀÎϘèɍä gÀDzǵ ȸ ǦĦǁÀÔöä ţÂφ özȑ Ž āäÀÎϘèɍä ÙÛƯ ÒĦÀΛş ÛTS ÿzΛåzÔöä ÆƎÊõşøÆƎȽ/ÿzƎöşÂöä ɄȝÀæø ȧøäüæ æÀǩ ÛåƎϘö ÕÀϘǩ ÛĘəÀęå ŌÔĦϘÊΛ ɄøϘöä ǦĦŌGöä ȸ gÆì ÀǯŌǗ ÛǴƎÊƎəÀöä ǦĦŌGöä Ƙȡ ÛA òzŸǂÀæ ÀȚƎŸȝ ŌÔĦϘÊΛ ǦĦŌæ ǴΛǗ ɉzÒǩ ɍ .øÀȚΛöä

.B òzŸǂÀæ ÀȚƎŸȝ

5 ȤÀƩ ÜŌȠ 100 ǰϘΛƎö R òzφÀǯƎţä ȸ ǴƎzÀŌ ǴƎȶŌ Ž ÛǴƎüzGŘȠ ǴφşàzȠ ÛȠŸȠ 20 ǴæäÀę āäØł :**Assay** ǦÊΛÀŌţä

ǴƎǵ Ž ȤÀÅţä òzŸǂä ȸ ȴè 1 ǴφÀÅǯæ ǦŌGü òŸǹ îÀȶϘöä āÀƎŌæ .¢ÊÀφ ÆΛØţÀæ ŌȠ 100 ɃǗ òzŸǂä äØȽ ȸ ŌȠ ğÀϘƎèǗ òzŸȚ ȝȠ ǴφøÀŌţÀæ øÀGΩǹɍä gÅȠ Ž $C_{23}H_{30}O_6$ ǴƎȶŌ ÆÊƠ .ÀϘȠzφÀφ 243 ÀȚzü ǴDZzȠ ÆΛȝ ɄȶȚȝɉä

âÀĔÕɳ ÿäÆÅϘèÀæ 0.02 ± 0.37 ȖȞDZÀţä ȯζŸǂä î ÀǬ ȷζȮʎ ȷÜ Ǣƶ .ȸɳäÂϘöäȿ ǦŏÀÎţÀæ î ζHʋÀţä ÛRS ȷζöȿÂĔφǻƎöä
.ÄĔζÀõ äĶĔĦǩ ÀɲĦɳ Ȗəζȑ ȤĔù

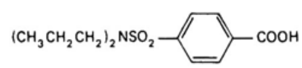
PROBENECIDUM

Probenecid ɋĭƨĭďĭǦǋƥǦǁɛ

$C_{13}H_{19}NO_4S$:**Molecular formula** ǦĔÀʌÂƨä Ǧ8ĔÔöä

285.4 :**Relative molecular mass** ǦĔǦÊÀöä ǦĔÀʌÂƨä ǦŸϘȮöä

:**Graphic formula** ǦĔφÀĔǦţä Ǧ8ĔÔöä



:**Chemical name** ȖəÀĔȶĔȮöä ȴèɍä

p-(Dipropylsulfamoyl)benzoic acid; 4-[(dipropylamino)sulfonyl]benzoic acid; CAS Reg. No. 57-66-9.

.ǦHʋəÀöä ȻÆʒ ÛĬĔǦʌÀÕǩ ȐĔæÜ ȿÜ ȐĔæÜ ȷζŸæ ȧζHʋÊɳ :**Description** Ȥòζöä

ȸɳ äŏÂDZ 12ȿ TS (ȯ/ȟ 750~) ȯζφÀǯʌɋä ȸɳ äŏÂDZ 25 Ž āäȿæ ÛĬĔŸȶʒ ŏÀţä Ž āäȿæ ɍ :**Solubility** ǦĔφÀæȿØöä
.ǦʌζŸÕöä ğäÆĔÊõȿøÆĔTä ȸɳ ǦÀÀÅţä ÕĔöÀǂä Žȿ R ÿǿζζȿǿζŸȮöä Ž āäȿæ ÜR ȷζϘĔèɉä
.â ÀÕĀŸö ǻÀȒɳ öäȿǻ :**Category** ǦÀÀöä

.ĬÆĔDZ ǦŐŸ8ɳ ǦʌȿÀǵ Ž ÆĔÊĔÆĔäȿƎöä ȘÀʒ ȷÜ Ǣƶ :**Storage** ȸʌÂÅϘöä

REQUIREMENTS ƘǦǁǯʊǓƘdž!ƒ

%101.0 ȸʒ ÆʌÂʌ ɍȿ %98.0 ȸʒ ÕĀʌ ɍ Àɳ ʔŸʒ ÆĔÊĔÆĔäȿƎöä Ƀζϙʓ :**General requirement** ÿÀʒ ÆŸÛϘɳ
.ǦÀĀÕä ǵǻÀţä БÜ ţζDZÀöÀæ ǦäζÊȚ Û$C_{13}H_{19}NO_4S$ ȸɳ

:**Identity tests** ɦĭǋǋǈɛ l ɛþƑǴǬɛ

• ȸȮƺ ĘĔǦÛǩ Àɳ Ü ǿÀǬɳɍä ȿÜ ȻÆǵȿ A ǿÀǬɳɍä ȸʌǿÀǬɳ B ȿC.

Spectrophotometry in [illegible] :A [illegible] .(43 [illegible] 1 [illegible]) "the infrared region [illegible] RS [illegible].

A [illegible] :B [illegible] B [illegible].

.°199 [illegible] :C

[illegible] 1.0 [illegible] :**Heavy metals** [illegible] (127 [illegible] 1 [illegible]) 3 [illegible] "Limit test for heavy metals" [illegible] (128 [illegible] 1 [illegible]) A [illegible] 20 [illegible].

[illegible] 1.0 [illegible] :**Sulfated ash** [illegible]

5.0 [illegible] 105° [illegible] :**Loss on drying** [illegible].

30 [illegible] 100 [illegible] 2 [illegible] :**Acidity** [illegible] TS [illegible] 0.15 [illegible] 0.5 [illegible] VS (0.1 [illegible]) [illegible].

[illegible] :**Related substances** [illegible] R4 [illegible] (84 [illegible] 1 [illegible]) "Thin-layer chromatography [illegible] TS (~17 [illegible]) [illegible] R [illegible] -1 [illegible] 15 [illegible] (A) [illegible] :TS (~750 [illegible]) [illegible] 9 [illegible] TS (~17 [illegible]) [illegible] 0.050 (C) [illegible] RS [illegible] 10 (B) [illegible] 10 [illegible] 20 [illegible] .B [illegible] A [illegible] 1 [illegible] .C [illegible] A [illegible] .(254 [illegible]) [illegible] A [illegible] .B [illegible] .C

[illegible] TS [illegible] 50 [illegible] 1.0 [illegible] :**Assay** [illegible]

.ÀĤÎŧõ TS ỏɀȹǰǊ/ỏɀŧǉɀɳʂƎöä Ǧęǿà ȳäǼǺǪèǺæ ÛVS (ỏ/ỏɀɳ 0.1) ğǺȹɀæÀỎöä ȸɳ БǺƪä ȳɀǺǻɀÔöä ǼǈÊõʂǿǼǈő ȸɳ БǺƪä ȳɀǺǻɀÔöä ǼǈÊõʂǿǼǈĿ ȸɳ Ŏɳ Ŏõ ùɀǺỎǺ .ǦǺǿʂÀȒöä ğǺǶǈǶÔǪöä ʔÀθʂ ǿǺǦǪǹɟä ɠǻǺɳ ȷʂǻ ǦǈŸŧȞöä ǻǺȞǩ

.$C_{13}H_{19}NO_4S$ ȸɳ ŋŸɳ 28.54 VS (ỏ/ỏɀɳ 0.1) ğǺȹɀæÀỎöä

PROCAINI BENZYLPENICILLINUM

Procaine benzylpenicillin ǄƖǂƨǆǦ üǐȒǆǦ ǄƖǐƒǀǋƥǦ

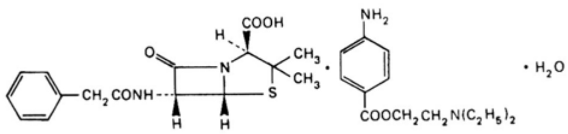
Procaine benzylpenicillin (non-injectable) (ǄƨΘǂǁ üǦƽ ƥǐƷ) ǄƖǂƨǆǦ üǐȒǿǆǦ ǄƖǐƒǀǋƥǦ

Procaine benzylpenicillin, sterile !ǐƨϒ ÛǄƖǂƨǆǦ üǐȒǿǆǦ ǄƖǐƒǀǋƥǦ

$C_{16}H_{18}N_2O_4S,C_{13}H_{20}N_2O_2,H_2O$:**Molecular formula** ǦǈǺÂƨä Ǧ8ǈÔöä

588.7 :**Relative molecular mass** ǦǈǦÊǺöä ǦǈǺÂƨä ǦŸǪỎöä

:**Graphic formula** ǦǈȹǺǈǦţä Ǧ8ǈÔöä



:**Chemical name** ȗǝǺǈŧǈỎöä ǀèɟä

2-(Diethylamino)ethyl *p*-aminobenzoate compound with (2*S*,5*R*,6*R*)-3,3-dimethyl-7-oxo-6-(2-phenylacetamido)-4-thia-1-azabicyclo-[3.2.0]heptane-2-carboxylic acid (1:1) monohydrate; 2-(diethylamino)ethyl 4-aminobenzoate compound with [2*S*-(2α,5α,6β)]-3,3-dimethyl-7-oxo-6-[(phenyl-acetyl)amino]-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid (1:1) monohydrate; CAS Reg. No. 6130-64-9 (monohydrate).

.ƙŸÊǺæ ƙǺǺõʂǺæ ÛG ƙŸÊǺæ ƙǺǺõʂǺæ :**Other names** ʔǺǹǛ őǺƧǛ

.ǺǦǺÄǩ ǦǶǝäÀöä ƇǼƷ ʂǛ ǦǶǝäÀöä ƇǼƷ ǛǺǦǺÄǩ ȀǈǼǛ ʂǛ ȀǈǼǛ ȧɀǶÊɳ :**Description** Ȥòɀöä

.R ȳǿɀɀʂǿɀŸỎöäʂ TS (ỏ/ȟ750~) ỏɀȹǰǊǪä Ž āäʂæ ÜöǺţä Ž ȷǺæʂǾöä ǴǈǶì :**Solubility** ǦǈȹǺæʂǾöä

.ǀǈǪäÀƨä ǻǺȒɳ őäʂǻ :**Category** ǦǺǺöä

ȷǛʂ ÛőɀȒöä ȸɳ ǦǈŧƮ ÛȳǺỎǵǜæ ǦŎŸ8ɳ ǦǺʂǺǵ Ž ƙŸÊǺæ ŌǺÂǿǺæ ƙǺǺõʂǺæ ȘǺƷ ȷǛ Ǽƶ :**Storage** ȸǺÂǺǪöä

[illegible] 30° [illegible].

Labelling [illegible]

Additional information [illegible]

REQUIREMENTS [illegible]

General requirement [illegible] 96.0% [illegible] 100.5% [illegible] $C_{16}H_{18}N_2O_4S, C_{13}H_{20}N_2O_2$ [illegible] 38.5% [illegible] 41.5% [illegible] $C_{13}H_{20}N_2O_2$ [illegible].

Identification tests [illegible]

A: [illegible] 0.05 [illegible] 2 [illegible] 2 [illegible] (~1760 [illegible]) TS [illegible] 2 [illegible] TS [illegible]

B: [illegible] 10 [illegible] 10 [illegible] 0.5 [illegible] TS [illegible] VS (0.01 [illegible]) [illegible] 1.0 [illegible] TS [illegible].

C: [illegible] 0.05 [illegible] General "identification [illegible] 1 [illegible] 119 [illegible]) [illegible].

Water [illegible] Determination of water by "the Karl Fisher Method [illegible] 1 [illegible] 145) A [illegible] 0.5 [illegible] 28 [illegible] 42 [illegible].

pH Value [illegible] 3.0 [illegible] 10 [illegible] 5.0 – 7.5.

:**Assay** [illegible]

[illegible] 1000 [illegible] 0.045 [illegible] 10.0 [illegible] 2.0 [illegible] 25 [illegible] °60 [illegible] TS [illegible] 10.0 [illegible] (A [illegible]) [illegible] °20 [illegible] .(B [illegible])

[illegible] 314 [illegible] 1 [illegible] A [illegible] TS [illegible] 10.0 [illegible] 2.0 [illegible] .B [illegible]

[illegible] B [illegible] A [illegible] $C_{16}H_{18}N_2O_4S,C_{13}H_{20}N_2O_2$ [illegible] 0.050 [illegible] .$C_{16}H_{18}N_2O_4S,C_{13}H_{20}N_2O_2$ [illegible] 1.601 [illegible] ($C_{16}H_{17}N_2NaO_4S$) RS [illegible] 0.03 ± 0.62 [illegible]

[illegible] 5 [illegible] 10 [illegible] 0.5 [illegible] R [illegible] 25 [illegible] TS [illegible] 75) [illegible] 20.0 [illegible] TS [illegible] 0.25 [illegible] VS [illegible] 0.1) 23.63 VS [illegible] 0.1) [illegible] 1 [illegible] .VS [illegible] 0.1) [illegible] .$C_{13}H_{20}N_2O_2$ [illegible]

[illegible]

Additional Requirements for Sterile Procaine Benzyl penicillin

"*Test for non injectable preparations* [illegible] .(32 [illegible] 5 [illegible])

[illegible] :**Bacterial endotoxins** [illegible] 30 [illegible] 5 [illegible]) "Test for Bacterial endotoxins [illegible] 0.01 RS [illegible]

Sterility testing of [illegible] :**Sterility** [illegible] TS [illegible] 162 [illegible] 1 [illegible]) "antibiotics

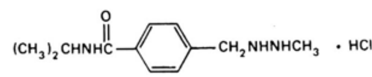
PROCARBAZINI HYDROCHLORIDUM

Procarbazine hydrochloride [illegible]

$C_{12}H_{19}N_3O,HCl$:**Molecular formula** [illegible]

257.8 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

N-Isopropyl-α-(2-methylhydrazino)-*p*-toluamide monohydrochloride; *N*-(1-methylethyl)-4-[(2-methylhydrazino)methyl]benzamide monohydrochloride; CAS Reg. No. 366-70-1.

[illegible] :**Description** [illegible]

[illegible] (~750 [illegible]) [illegible] :**Solubility** [illegible]

[illegible]

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

[illegible] 223° [illegible] :**Additional information** [illegible]

REQUIREMENTS [illegible]

[illegible] 98.5% [illegible] :**General requirement** [illegible] 100.5% [illegible] $C_{12}H_{19}N_3O,HCl$ [illegible]

:**Identity tests** [illegible]

Spectrophotometry in ŏäÀŧΣä ǨƠ ǦȫÛÀţä Ž ȖəζȒöä ǅĔÛöä âÀĔę" ȷäζÀȝ ǨƠ Ȣζòζţä øÀǤǫǹŧä ĘǤÛŀ :A ȡȝ ǰǨÀöä ǅĔÛöä Ȝŋ ŏäÀŧΣä ǨƠ ǦȞìɉä îÀÔǫŋä ǅĔù ĘǣÀÛǪ .(43 ǦȞÀÔöä Û1 ÆŸŎä) "the infrared region .ȡǪäÀǣøÀõşƎöä ÆǪøζŸõşøÆĔT ȖȞDZÀţä ǅĔÛöä Ȝŋ şǕ RS ȡǪäÀǣøÀõşƎöä ÆǪøζŸõşøÆĔŁ

General ǦŋÀȞöä ȢäÀȞǫèŧä ğäøÀǤǹä" ȷäζÀȝ ǨƠ Ȣζòζţä B ŌȝÀÀǫöä Ōŋ/ȟ 0.10 ÂĔõÀǫǣ ȯζŸȚ ȖÛȞǪ :B .(121 ǦȞÀÔöä Û1 ÆŸŎä) ğäÆǪøζŸȮŸö ÂĔŧŧõ "identification tests

øÀǤǹŧä" ȷäζÀȝ ǨƠ Ȣζòζŋ ζȽ Àŧõ ȟ 1.0 ŌŧȞǫÊǪ øÀǤǹŧä ȯζŸȚ ƘȒȞǫö :Heavy metals ǦŸĔȭǯöä ȷåÀȞţä ȡŋ Ɂζǫǂä åÆȜ Ǖ(127 ǦȞÀÔöä Û1 ÆŸŎä) 1 ǦȫǪÀÛöä ÆÊɎ "Limit test for heavy metals" ǦŸĔȭǯöä ȷåÀȞŧŸö ɃÆΣä .ȟ/ÿäÀɖşÀÒŋ 20 äşÀDZǪ ŧ Ǖ(128 ǦȞÀÔöä Û1 ÆŸŎä) A ǦȫǪÀÛŸö ǨȫζşǦŸĔȭǯöä ȷåÀȞţä

.ȟ/ŊŸŋ 1.0 ȡŋ ÀǯõǕ ÈĔö :Sulfated ash ǨÀŸÊţä åÀŋÀöä

5 ȡŋ ÀǯõǕ ÆȭÀǪ ŧ Ǖ°ÿ105 ğøäÀǵ ǦDZøÆǣ ǨǣÀǯöä ȷàζöä ɁøǫǵǅǺƶ :Loss on drying ǅĔÀDZǫõÀǣ ÆȭÀöä .ȟ/ŊŸŋ

.4.5 – 3.0 ÛŌŋ/ȟ 0.05 ÂĔõÀǫǣ ȯζŸȚ öÀȽÀǣ :pH Value öÀȽÀǤöä ǦŧĔę

1080~) ȭĔŋøζÀöä Ȑþ ȡŋ Ōŋ 5 ȡŋ ǰǪÂŋ Ž ÛǤĔùζǤȒŋ ǤǫşàζŋÛȟ 0.125 ǦǣäÀę ǡäǾŀ :Assay ǦÊǪÀȫţä ÛTS ȭĔǫĔèɉä Ȑþ/ȭĔȫǤǝÂöä ğÀǫĔèǕ ȯζŸȚ ȡŋ Ōŋ 5 ȢÀȒǪ ÛR1 ȖDZŸǯöä ȭĔǫĔèɉä Ȑþ ȡŋ Ōŋ 20ş TS (ȯ/ȟ Non- ȖəÀţä ŧ ǕèζöäŽ ǥÀǪȞţä" ȷäζÀȝ ǨƠ Ȣζòζŋ ζȽ Àŧõ VS (ȯ/ȯζŋ 0.1) ȭǪøζŸõƘǤöä Ȑþ Ȝŋ ÀǪȞǪş VS (ȯ/ȯζŋ 0.1) ȭǪøζŸõƘǤöä Ȑþ ȡŋ Ōŋ 1 Ȭõ .(142 ǦȞÀÔöä Û1 ÆŸŎä) A ǦȫǪÀÛöä Û"aqueous titration .$C_{12}H_{19}N_3O,HCl$ ȡŋ ŊŸŋ 25.78 ǜζÀÒǪ

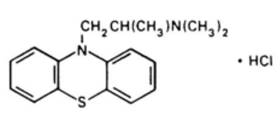
PROMETHAZINI HYDROCHLORIDUM

Promethazine hydrochloride ǅǰȒƙǐǅǍǈþǤǁǫ ǫǐþǋɉǀǋþǫǐǉ

$C_{17}H_{20}N_2S,HCl$:**Molecular formula** ǦĔÀǪÂƨä ǦȢĔÔöä

320.9 :**Relative molecular mass** ǦĔǤÊÀöä ǦĔÀǪÂƨä ǦŸǫȮöä

:**Graphic formula** ǦĔǬÀĔǤţä ǦȢĔÔöä



Chemical name:

10-[2-(Dimethylamino)propyl]phenothiazine monohydrochloride; *N*,*N*,α-trimethyl-10*H*-phenothiazine-10-ethanamine monohydrochloride; CAS Reg. No. 58-33-3.

Other name: Diprazinum.

Description:

Solubility: (~750) TS R

.R

Category:

Storage:

Additional information:

REQUIREMENTS

General requirement: 98.5% 101% $C_{17}H_{20}N_2S,HCl$

Identity tests:

A: 20 5 0.05 (IV) R

B: 0.25 25 25 (7) TS 10 160 (~750) TS

C: 0.05 5 2 (~1000) TS A "General identification tests (121)

Solution in chloroform: 1.0 10 R

Ywl

.(53 [illegible] 1 [illegible]) "Colour of liquids [illegible]

[illegible] 1.0 [illegible] :**Sulfated ash** [illegible]

5.0 [illegible] 105 [illegible] :**Loss on drying** [illegible]

.5.0 - 3.5 [illegible] 0.10 [illegible] :**pH Value** [illegible]

[illegible] :**Related substances** [illegible] R4 silica gel [illegible] (84 [illegible] 1 [illegible]) "Thin-layer chromatography [illegible] 5 [illegible] R [illegible] 10 [illegible] R [illegible] 85 [illegible] 95 [illegible] 10 [illegible] R [illegible] 20 (A) [illegible] :R [illegible] 5 R [illegible] 0.20 (B) [illegible] 254) [illegible] .B [illegible] A

[illegible] 10 [illegible] R [illegible] 200 [illegible] 0.4 [illegible] :**Assay** [illegible] TS [illegible] 3 TS [illegible] A [illegible] Non-aqueous titration [illegible] VS (0.1 [illegible]) [illegible] 32.09 [illegible] VS (0.1 [illegible]) [illegible] 1 [illegible] .(142 [illegible] 1 [illegible]) $C_{17}H_{20}N_2S,HCl$ [illegible].

[illegible]

Additional Requirements for Promethazine hydrochloride for parenteral use

.(56 [illegible] 4 [illegible]) "*Parenteral preparations* [illegible]

[illegible] :**Bacterial endotoxins** [illegible] (30 [illegible] 5 [illegible]) "Test for Bacterial endotoxins [illegible] 5.0 RS [illegible].

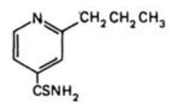
PROTIONAMIDUM

Protionamide [illegible]

$C_9H_{12}N_2S$ **:Molecular formula** [illegible]

180.3 **:Relative molecular mass** [illegible]

:Graphic formula [illegible]



:Chemical name [illegible]

2-Propylthioisonicotinamide; 2-propyl-4-pyridinecarbothio-amide; CAS Reg. No. 14222-60-7.

[illegible] **:Description** [illegible]

[illegible] TS [illegible] (750~) [illegible] **:Solubility** [illegible]

.R [illegible] R [illegible]

.[illegible] **:Category** [illegible]

.[illegible] **:Storage** [illegible]

REQUIREMENTS [illegible]

%101.0 [illegible] %98.0 [illegible] **:General requirement** [illegible]

.[illegible] $C_9H_{12}N_2S$ [illegible]

:Identity tests [illegible]

• .D [illegible] C [illegible] B [illegible] D [illegible] A [illegible]

Spectrophotometry in [illegible] **:A**

[illegible] "the infrared region [illegible] (43 [illegible] 1 [illegible])

.[illegible] RS [illegible]

230 [illegible] TS (750~) [illegible] 10 [illegible] **:B**

ĞDZζţă ȯζù Ž ˌè 1 ǴφǺǺǯæ ĞŎĞù Ǝȝ î Ǻŧǫöă ȷζȮǺ ÜǺǫηζφǺφ 291 ȯζÛöă ǼǺȝ ǴŁŧŢȝǓ Ǵŧŀę ÛǺǫηζφǺφ 350ş ǺǫηζφǺφ .0.39 ǴăăǺę ăØŁ

ğǺǫŀèǓ Ǵęóş ĞΘǺǺöă ĝǺŊɉă ŎȞΘ Üvs (ȯ/ȯζɳ 1) ǼǺøζŶÕşøǼŀŢă Ȑƥ ȸɳ Ŏɳ 5 Ž ȟ 0.1 ȸǺǺÊǺ :C .ŏăǻζè R î ǺȍǺöă

.°ÿ141 ǴăăǺę ÛøǺŽÔφɍă ĞDZøǻ :D

øǺǫǹɍă" ȷăζǺȝ ǨƠ Ȣζȍζɳ ζŁ Ǻŧõ ȟ 1 ŎŧȞǫÊǺ øǺǫǹɍă ȯζŶŢ ǨȒȞǫö :**Heavy metals** ĞŶŀŎǯöă ȷǻǺȞţă ȸɳ Ɂζǫǂă ƙȞǺ Ü(127 ĞȞǺÔöă Û1 ǼŶŎă) 3 ŏăǺDZɋă ǼÊɯ "Limit test for heavy metals" ĞŶŀŎǯöă ȷǻǺȞŧŶö ɃǼΣă .ȟ/ÿăǺɖşǺȮɳ 20 ăşǺDZǫǺ ɍ Ü(128 ĞȞǺÔöă Û1 ǼŶŎă) A ĞŎǺǺÛŶö ǺŎζş ĞŶŀŎǯöă ȷǻǺȞţă

.ȟ/ɳŶɳ 1.0 ȸɳ Ǻǯõǔ Ȅŀö :**Sulfated ash** ǨǺŶÊţă ǻǺɳǺöă

5.0 ȸɳ Ǻǯõǔ ǼŎǺǺ ɍ Ü°ÿ105 ĝøăǺǵ ĞDZøǼæ ǨæǺǯöă ȷàζöă ɂøǫǵ ƵǺƶ :**Loss on drying** ƵŀǺDZǫǺæ ǼŎǺöă .ȟ/ɳŶɳ

ǫǼȜ ɂøǫǵ ǯǺŀ ÛǻƎǺ ÛöǺɳ Ŏɳ 20 ȢǺȒǺ ÛR ùζăǼöă ȯζφǺǯŀţă ȸɳ Ŏɳ 20 Ž ȟ 2.0 āăØŀ :**Acidity** Ğȑζŧ Σă ǼŶÛǫǺ ɍ ÜǺȞÎŧõ TS ȯζφǺǯǺǓ/ȯşǺǺȮöă ĝǺƥ ȯǺŧȞǫèǺæ Üvs (ȯ/ȯζɳ 0.1) ÿζǺǻζÔöă ǼŀÊÕşøǼŀõ ǺǺȞǺş ÛøζŶĞǫöă .(ƂǺŎǨǺæ) ǺȞÎţă ȸɳ ĞÛèζǫţă ĞÛŎǺöă ɁŶȝ ȯζÔȞŶö Ŏɳ 0.2 ȸɳ Ǻǯõǔ Ǻɳɉă

ĞŎŀęǺöă ĞŎĞÛöă āăǺÎǫèă" ȷăζǺȝ ǨƠ Ȣζȍζɳ ζŁ Ǻŧõ øǺǫǹɍă ĘĞÛǺ :**Related substances** ĞŏǺÎţă ǻăζţă ĞŶǼȢɳ ĝǻǺŧõ R4 silica gel ǺȮŀŶŀÊöă ĞɳƳŁ ÿăǼǺǫèǺæ (84 ĞȞǺÔöă Û1 ǼŶŎă) "Thin-layer chromatography ĞȞŀǺÔöă ɁŶȝ ƳÔǺǺɳ ĘĞÛŀ .õǺȞǫɳ øζÛõ R ȯζφǺǯŀţă ȸɳ ǼǵăşǺDZǵş ÛR ÿøζζşøζŶȮöă ȸɳ ÿζDZǵ 9 ȸɳ ǰǺǺɳş ĝǻǺɳ ȸɳ ɳŶɳ 0.25 (B)ş Ǻǫö ɄŶŀţă Ž øǺǫǹɍă ĝǻǺɳ ȸɳ ɳŶɳ 50 (A) Ƀζȝ :R ȯζφǺǯŀţă Ž ƙȯζŶŢ ȸɳ ǺǫöşǺȮɳ 5 āăǺÎǫèɍă ÙÛƯ ȎȞǺǺş ŏăζŢă Ž ƵDZǫö õǺǫǨ ÛāăǺ Îǫèɍă ĝǺDZǵ ȸɳ ĞȞŀǺÔöă ţǺφ ǼȞæ .Ǻǫö ɄŶŀţă Ž øǺǫǹɍă ÛĞŀÊŀǝǺöă ĞȞŎĞöă ŏǺǺǯǫèǺæ ÛA ȯζŶǂǺæ ǺŽŀŶȝ ŎÔȞǫÊǺ ĞȞŎæ ĞǺǓ ȷζȮǨ ɍ .(ǺǫηζφǺφ 254) ĞŀDZÊǺǺĞöă ȧζζ ĞȞȉɉă ŏζȒæ .B ȯζŶǂǺæ ǺŽŀŶȝ ŎÔȞǫÊǺ Ʉøǫöă ĞȞŎĞöă ȸɳ ĝǼȉ Ǻǯõǔ

ȝɳ ǺǺȞǺş ÛR1 ɄDZŶǯöă ȰŀǫèɉăȐƥ ȸɳ Ŏɳ 30 Ž ÛĞŀùζĞȒɳ Ǵφşàζɳ Ûȟ 0.45 ǴăăǺę āăØŀ :**Assay** ĞÊǺǺŎţă Non-aqueous ɄǝǺɳŶöă Ùèζöă Ž ĝǺǺȞţă" ȷăζǺȝ ǨƠ Ȣζȍζɳ ζŁ Ǻŧõ vs (ȯ/ȯζɳ 0.1) ȰǺøζŶÕƘĞöă Ȑƥ 18.03 ùζǺȮǺ vs (ȯ/ȯζɳ 0.1) ȰǺøζŶÕƘĞöă Ȑƥ ȸɳ Ŏɳ 1 Ŏõ .(142 ĞȞǺÔöă Û1 ǼŶŎă) A ĞŎǺǺÛöă Ûtitration .$C_9H_{12}N_2S$ ȸɳ ɳŶɳ

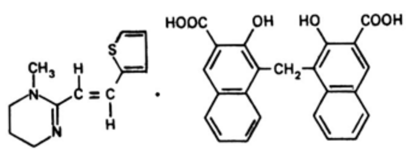
PYRANTELI EMBONAS

Pyrantel embonate

$C_{11}H_{14}N_2S,C_{23}H_{16}O_6$:**Molecular formula**

594.7 :**Relative molecular mass**

:**Graphic formula**



:**Chemical name**

(*E*)-1,4,5,6-Tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine compound with 4,4′-methylenebis[3-hydroxy-2-naphthoate] (1:1); (*E*)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)ethenyl]pyrimidine 4,4′-methylene-bis[3-hydroxy-2-naphthalenecarboxylate] (1:1); CAS Reg. No. 22204-24-6.

.Pyrantel pamoate :**Other name**

:**Description**

:**Solubility**

:**Category**

:**Storage**

REQUIREMENTS

%97.0 :**General requirement**

$C_{11}H_{14}N_2S,C_{23}H_{16}O_6$ %103.0

:**Identity tests**

.D C B A •

Spectrophotometry in :A

ȸȝ ǰǨȂǚǟ ǽƔǕǚǟ ȝȡ ǚǟȂȶΣǟ ǨƠ ǦȀǐ ǿǟ ǐȂǑǫȡǟ ǽƔǝ ǅǠȂǕǫȂ .(43 ǦȆȂǑǚǟ Ǖ1 ǼǛǑǟ) "the infrared region
.ǑȈǫǟǨǦǚǟ ǧȂǫƓǫǢ ȺǶǮȂǗǟ ǽƔǕǚǟ ȝȡ ȘǕ RS ǑȈǫǟǨǦǚǟ ǧȂǫƓǫǢǕ ǻǫǛǓ

230 ǨǞ ǦǮǫǗǟ ǻǫǕǞ ¢ǨǼȊǛǐȡ ǼǞȝ ǕR ǻǫǭǰǼǗǟ Ž Ǒȡ/ȳǟǛȡȘǛǑȡ 13 ǛǼǑǛǞ ǻǫǛǓ ǐǛǑǫȡǟ ǽƔǝ ȺǕǨǛ :B
ǻǫǕǞ ǐǛȶǫǚǟ ǦǦǊǫ ȷǫǑǨ .ǛǫȡǫǭǛǫ 300ȘǨǦǛǑǨ ǛǫȡǫǭǛǫ 288 ǦǮǫǗǟ ǻǫǕǞ ǨǫȶȚȝǕ ǨǫȶȨ ǕǛǫȡǫǭǛǫ 360Ș ǛǫȡǫǭǛǫ
.ǨǦǛǑǨ 1.0 ǛǫȡǫǭǛǫ 300 ǦǮǫǗǟ ǻǫǕǞ ǐǛȶǫǚǟ ƂǕ ǛǫȡǫǭǛǫ 288 ǦǮǫǗǟ

ǻǫǛǓ ȸȡ Ǒȡ 1.0 ȣǛȐǛȘ TS (ǻ/ȟ 70~) ǑǛǼǫǛǑȘǼǨǨǓǟ Ȑþ ǻǫǛǓ ȸȡ Ǒȡ 1.0 Ž ȠǛȡ 5 ǟǟǾǛ :C
.ƆǟǫǮǼǕ ȷǫǐ ǰǫǛǛ ǕTS ǑǛǼǫǛǊǟ Ȑþ/ǼǨǨǼǚǛȠǼǫǛǚǟ

.ǑǐǛǫǚǟ ȝȡ °ȳ250 ȧǫǫ ǕǼǛǪǑǫȓǟ ǦǮǼǟ :D

.ȟ/ȠǛȡ 5.0 ȸȡ ǛǆǑǕ ǊǨǚ :**Sulfated ash** ǨǛǛǊǗǟ ǟǛȡǛǚǟ

0.6 ȸȡ ǛǆǑǕ ǊǨǚ) ȐǛǺǛȡ Ǖȣȓ ǨƠ °ȳ60 ǥǼǟǛǥ ǦǮǼǼǞ ǽǟȥ :**Loss on drying** ǽǨǛǮǫǚǟǞ ǼǑǛǚǟ
.ȟ/ȠǛȡ 20 ȸȡ ǛǆǑǕ ǼǑǛǛ ȓ ǕǧǛȝǛǛ 3 ǥǼȡ (ȺǑǦǚǟ ȴǛȡ 5 ǦǟǟǛȨ ȘǕ ǻǛǑǛǛǟǫǛǨǑ

ǦǑǨȨǛǚǟ ǦǑǦǕǚǟ ǟǟǛǐǫǛǟ" ȷǟǫǛȝ ǨƠ ȣǫǻǫȡ ǫȽ ǛȶǑ ǼǛǦǫǻȓǟ ȨǦǕǛ :**Related substances** ǦǑǛǐǗǟ ǟǟǫǗǟ
ǦǛǨȣȡ ǥǟǛȶǑ R2 silica gel ǛǑǨǛǨǊǚǟ ǦȡƳȽ ȳǟǼǺǫǛǛǟ (84 ǦȆȂǑǚǟ Ǖ1 ǼǛǑǟ) "Thin-layer chromatography
R ǨȡƳǨǆǛǕ ȺǟǛǫ ȸȡ ǛȶǮǥ 1.5Ș ǕR ǻǫǭǰǼǗǟ ȸȡ ȳǫǮǥ 5Ș ǕR ǑǨǆǛǫǟ ǧǛǫǨǛǕ ǻǫǛǓ ȸȡ ǛȶǮǥ 20 ȸȡ ǰǛǛȡȘ
5Ș R ȳǼǫǫȘǼǫǛǑǚǟ ȸȡ ȳǫǮǥ 5 ȸȡ ǰǛǛȡ Ž ǨǻǫǛǓ ȸȡ ǛǫǑȘǛǑȡ 100 ǦȆǨǛǑǚǟ ȝǛȝ ǛǑǛǛȡ ȨǦǕǨ .ǑǛȆǫȡ ǼǫǕǑ
0.20 (B)Ș ǼǛǦǫǻȓǟ ǥǟǛȡ ȸȡ ȠǛȡ 20 (A) Ƀǫǅ :TS (ǻ/ȟ 260~) ǛǨǫȡȷǟ ȸȡ ȴǮǥ 0.5Ș R ǻǫǭǰǼǗǟ ȸȡ ȳǫǮǥ
ȨǟǛȨǟ 10 ǥǼȡ ǚǟǫȚǟ Ž ǽǮǫǚ ǑǛǫǨ ǕǟǟǛǐǫǛȓǟ ǥǛǮǥ ȸȡ ǦȆǨǛǑǚǟ ȶǛǫ ǼǞǟ .ǛǫǑ ȺǛǨǗǟ Ž ǼǛǦǫǻȓǟ ǥǟǛȡ ȸȡ ȠǛȡ
ǻǫǛǂǛǟ ǛǪǨǛȝ ǑǑȆǫǊǛ ǦǑǟ ǦǛǕ ȷǫǑǨ ȓ .(ǛǫȡǫǭǛǫ 254) ǦǨǮǊǛǛǦǚǟ ȧǫǫ ǦǨǐǫǟǞ ȺǼǟǟǛǐǫǛȓǟ ǕǕǺǗǟ ǑȆǛȘ
.B ǻǫǛǂǛǟ ǛǪǨǛȝ ǑǑȆǫǊǛ ȺǼǫǚǟ ǦǑǦǚǟ ȸȡ ǥǼǐ ǛǆǑǕ ǕǦǨǊǨǛǚǟ ǦǑǦǚǟ ǚǟǛǆǫǛǛǞ ǕA

:**Assay** ǦǊǛǑǗǟ

• ǧǟǞ ǦǨǮǛǮǛ ǦǨǫǕ ȳǟǼǺǫǛǟ ǑȐǛȘ ǕǥǼǛǼȡ interruptions ǧǛǨǐǛǑȡ ǦǛǕ ȷȘǟȘ ǨǫǛȠ ǚǫȓ Ž ǦǊǛǑǗǟ ƼǛθ
.**low actinic** ǦȐǛǺǛȡ ǦǨǛǫǨǑǕ

ȸȡ Ǒȡ 10 ȸȡ ǰǛǛȡ Ž ǟǟǾǨ ǕǑȡ 200 ǛǪǫǨǊ ǦȶǮǥ ǦǛǮǫǥ ƂǕ ǕǦǨǐǫǦȐȡ ǦǫȘǚǫȡ Ǖȟ 0.10 ǦǟǟǛȨ ǑǑǛ
(ǻ/ȟ 140~) ǑǛǼǫǛǑǨǦǚǟ ȐȶɯȴǮǥ ƂǕ ǽǛǅȘ ǕTS (ǻ/ȟ 100~) ǛǨǫȡȷǟ ǻǫǛǓ ȸȡ Ǒȡ 10Ș R ȷǛǊǑǫǛǼǚǟ
.Ǒȡ 50 ǛǪǫǨǊ ǦȶǮǥ ǦǛǮǫǥ ƂǕ ǦȨǛǦǚǟ ǦǥǛǐǛǚǟ ȸȡ Ǒȡ 5 ǑǑǛȘ ǕǦǥǛǐǛǚǟ ȸȡ Ǒȡ 10 ǻȘǕ ƼȡǛǛ ǕǦǐǛǛ .TS
ȣǛȐǛ ǕǑȡ 250 ¢ǫǨǊ ǑǑǫ ȝȶȨ ƂǕ Ǒȡ 25 ǑǑǛ .ǅǟȘȘ TS (ǻ/ȟ 140~) ǑǛǼǫǛǑǨǦǚǟ ȐȶɯȴǮǥ ƂǕ ǽǛǅ
ǐȳǺǫǊǟ ǟǛǨǛ .ȷǛǫ ǑǑǫ ȝȶȨ ƂǕ ȳǼǫǫȘǼǫǛǑǚǟ ǦǑǦǝ ǳǛǼǛǨ .ǛǼǨǮ ǅǛǛȘ ǕR ȳǼǫǫȘǼǫǛǑǚǟ ǻǫǛǓ ȸȡ Ǒȡ 100

100 ... VS (P ≤ 0.05) ... 40 ... 40 ... 100 ... VS (P ≤ 0.05) ... VS (P ≤ 0.05) ... 311 ... 1 ... $C_{11}H_{14}N_2S, C_{23}H_{16}O_6$ ... VS (P ≤ 0.05) ... RS ...

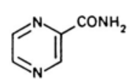
PYRAZINAMIIDUM

Pyrazinamide

$C_5H_5N_3O$ **:Molecular formula**

123.1 **:Relative molecular mass**

:Graphic formula



:Chemical name

Pyrazinecarboxamide; CAS Reg. No. 98-96-4.

:Description

TS (~750) ... **:Solubility**

:Category

:Storage

REQUIREMENTS

%101.0 ... %98.5 ... **:General requirement**

... $C_5H_5N_3O$ ...

:**Identity tests** ƕĭŇǰŇǁĚ ǀ ĘƥƑĜƗƢĘ

.DȘ C Ș B ğäøÅǪǹɍä șǕ ȻåÀÅɳ A øÅǪǹɍä ĘƗƓÛǨ ȸÒς ●

Spectrophotometry in õäÀȶΣä ǨƠ ǦÕÛÅƫä Ž ɄəȤȒöä ȤƗÛöä âÅƗę" ȷäȤÅȝ ǨƠ ȣȤòȤƫä øÅǪǹɍä ĘƓÛŀ :A ȸɳ ǰǨÅÅöä ȤƗÛöä ȝɳ õäÀȶΣä ǨƠ ǦǶìɉä îÅÔǪɳä ȤƗù ĘæÅÛǪÅ .(43 ǦĦÅÔöä Û1 ÆŸÕä) "the infrared region .ÆƗɳÅÅÀäÄƘǦŸö ɄǶDZÀƫä ȤƗÛöä ȝɳ șǕ RS ÆƗɳÅÅÀäÄƘǦö òȤŸƮ

350Ș ÀǪɳȤφÅφ 230 ƙæ ǦDZȤƫä òȤÛæ ȼǩÆȽÅĪɳ ÆÅȝ ÛŌɳ/ȳäÀɖșÀÒɳ 10 ÂƗõÀǪæ òȤŸƮ îÅÔǪɳä ȤƗù ɃÆǦÅ :B ǦŌǦù Ȝȝ îÅȶǪöä ɳŸǦÅ ÜÀǪɳȤφÅφ 310 ǦDZȤƫä òȤÛæ ÀȣòǕ ÀǹǛș ǨǦÅÀŌǨ ÀǪɳȤφÅφ 268 ǦDZȤƫä òȤÛæ ǨƗȶȚȝǕ ǨÆǵ ÛÀǪɳȤφÅφ .ǨǦÅÀŌǨ 0.66 ÀǪɳȤφÅφ 268 ǦDZȤƫä òȤÛæ ɭè 1 ǦφÅǺǯæ

ȷȤǒ ǰǪÅÅ ÜTS (ò/ȟ 15) àșÆÅÆΣä ğÅÅŸè òȤŸƮ ȸɳ Ōɳ 1 ȣÅȒÅș õÅƫä ȸɳ Ōɳ 10 Ž ȟ 0.1 āäØŀ :C .TS (ò/ȟ 80~) ȳȤÅåȤÔöä ÆƗÊõșøÆƗȽ òȤŸƮ ȸɳ Ōɳ 1 ǦȤÅȑüæ ȧøàɉä ɃǕ òȤĦǪÅ ÀƥɉäɃǕ āäøÅȑ ɃÅŌǨÀæ ōøÆǨ ɄøǪöä ÛÅƗφȤɳɉä ǰǪÅǨ ÜTS (ò/ȟ 200~) ȳȤÅåȤÔöä ÆƗÊõșøÆƗȽ òȤŸƮ ȸɳ Ōɳ 5 Ž ɳŸɳ 20 ȥŸȣÅ :D .ÅƬǪĦəäÀæ

.°ȳ191 – 188 ƙæ ǦDZøÆöÅæ :**Melting range** øÅƬÔφɍä òÅƒ

øÅǪǹɍä" ȷäȤÅȝ ǨƠ ȣȤòȤɳ ȤȽ ÅȶõȟĪ1.0 ŌȶǶǪÊÅ øÅǪǹɍä òȤŸƮ ƘȒĦǪö :**Heavy metals** ǦŸƗŌǯöä ȷåÅǶƫä ȜȤǪɉä ȸǷǶÅ Ü(127 ǦĦÅÔöä Û1 ÆŸÕä) 3 õäÀDZɋä ÆÊɰ "Limit test for heavy metals ǦŸƗŌǯöä ȷåÅǶƫä ŌDZɉ ɃÆΣä .ȟ/ȳäÀɖșÀÒɳ 20ȸȝ ÆÅÂÅ ɍ Ü(128 ǦĦÅÔöä Û1 ÆŸÕä) A ǦŌÅÀÛŸö ǨŌȤș ǦŸƗŌǯöä ȷåÅǶƫä ȸɳ

.ȟ/ɳŸɳ 1.0 ȸɳ ÀǯõǕ ÈƗö :**Sulfated ash** ǨÅŸÊƫä åÅɳÀöä

Determination of water by ÀĪƗȤ òøÅõ ǦŌÅÀÛæ õÅƫä ƙƗǶǨ" ȷäȤÅȝ ǨƠ ȣȤòȤɳ ȤȽ ÅȶõȸǷǶÅ :**Water** õÅƫä õÅƫä ȜȤǪƮ ÆÅÂÅ ɍ ÜǨǦÅÀŌǨ ǵåÅƫä ȸɳ ȟ1 ȳäÆǺǪèÅæ Û(145 ǦĦÅÔöä Û1 ÆŸÕä) A ǦŌÅÀÛöä Û"the Karl Fisher Method .ȟ/ɳŸɳ 5.0 ȸȝ

.7.0 -5.0 ÛR ȷȤæÀÒöä ÆƗÊõǕ ɄəÅφ ȸɳ òÅǹ õÅɳ Ž Ōɳ/ɳŸɳ 15 ÂƗõÀǪæ òȤŸƮ õÅȽÅæ :**pH Value** õÅȽÅǦöä ǦȶƗę

òȤŸƮ ȸɳ Ōɳ 1.0 R ȷȤæÀÒöä ÆƗÊõǕ ɄəÅφ ȸɳ ɃÅǃä õÅƫä ȸɳ Ōɳ 20 ɃǕ ȣÅȒÅ :**Ammonia** ÅƗφȤɳɉä ȸɳ ɃÅǃä ȳȤÅåȤÔöä ÆƗÊõșøÆƗȽ òȤŸĦɳ òÆǶǪÊÅ ÛTS òȤφÅǯǕ/ƙÅöÅǯȤ òȤÆÅöä ȸɳ Ōɳ 0.05Ș TS ÆƗȽÆöÅɳøȤÅöä ÀÅÅǶÅ .ƙǺÊǪöä ȝɳ øØɰ āäØÅș ÛøÅǪǹɍä ǵåÅɳ ȸɳ ȟ 0.50 ȣÅȒÅ ÛǵøșÀȒöä ÆÅȝ ÛVS (ò/òȤɳ 0.1) ğÅφȤæÀÒöä ȸɳ ÀǯõǕ ȳÂŸÅ ɍ ÜɄŸÅφÀę ȷȤǒ ǰǪÅÅ ȥøǪǵ VS (ò/òȤɳ 0.1) ğÅφȤæÀÒöä ȸɳ ɃÅǃä ȳȤÅåȤÔöä ÆƗÊõșøÆƗȽ òȤŸĦɳ .VS (ò/òȤɳ 0.1) ğÅφȤæÀÒöä ȸɳ ɃÅǃä ȳȤÅåȤÔöä ÆƗÊõșøÆƗȽ òȤŸƮ ȸɳ Ōɳ 0.50

ȸŋ Ōŋ 54ş R ÿǿźźşǿźŸȮöä ȸŋ Ōŋ 15 ȸŋ ǰĀÂŋ Ž ÛĞĔüźĜȒŋ Ǧφşàźŋ Ûȟ 0.07 Ǧäă ǟäǾł :**Assay** ǦȆĀǑţä 0.1) ǬĀǿźŸǬƘǦöä Ȍ þ Ʒŋ ÄĀĀȞĀş ÛĀȞȊ ŧõ TS ȷäǻźÊöä gÀþ ȸŋ Ōŋ 0.15 ȣĀȒĀ ÛR ǬĘǪĕɉä ǼĀǿǼĘŒÜ ȯźŸƮ ǼŸǑä) A ǦǑĀÀÛä ÛNon-aqueous titration ɄəĀŋƳöä Ǜèźöä Ž gÀĀĀȞţä" ȷäźĀʒ ƘƠ ȣźòźŋ źȽ Āŧõ VS (ȯ/ȯźŋ .$C_5H_5N_3O$ ȸŋ ŊŸŋ 12.31 ȕźĀȮĀ VS (ȯ/ȯźŋ 0.1) ǬĀǿźŸǬşƘǦöä Ȍ þ ȸŋ Ōŋ 1 Ǭõ .(142 ǦɄĀǑöä Û1

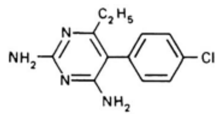
PYRIMETHAMINUM

Pyrimethamine ǅĩǅǰƘĩǅĭþĭǦǁɛ

$C_{12}H_{13}ClN_4$:**Molecular formula** ǦĘĀĀÂƨä ǦȣĘǑöä

248.7 :**Relative molecular mass** ǦĘĜÊĀöä ǦĘĀĀÂƨä ǦŸǪȮöä

:**Graphic formula** ǦĘφĀĘĜţä ǦȣĘǑöä



:**Chemical name** ɄəĀĘŧĘȮöä ȴèɍä

2,4-Diamino-5-(*p*-chlorophenyl)-6-ethylpyrimidine; 5-(4-chlorophenyl)-6-ethyl-2,4-pyrimidinediamine; CAS Reg. No. 58-14-0.

.ǦɄəäÀöä ǢǼʒ ÜȷźŸöä ȒĘæÜ ÛɃǿźŸæ ȧźɄÊŋ :**Description** Ȥòźöä

R ÿǿźźşǿźŸȮöäş TS (ȯ/ȟ750~) ȯźφĀǯĀqä Ž ȷĀæşǾöä ǴĘɄì ÜöĀţä Ž ǼĘŸŧʒ ǟäşǽ ɍ :**Solubility** ǦĘφĀæşǾöä .R ȷźǪĕɉäş

.ĀĀǿƳţä ǻĀȒŋ :**Category** ǦĀĀöä

.ǒźȒöä ȸŋ ʔŧɄł ȷÜş ÛǼǼĘǄ ǦǑŸȣŋ ǦĀşĀǵ Ž ƙŋĀǯĘƺƘǦöä ȘĀƷ ȷÜ Ǽƶ :**Storage** ȸĀÂǺǪöä

REQUIREMENTS ƘǦɄǀƱƙǆ!ƒ

%101.0 ȸʒ ǼĀÂĀ ɍş %99.0 ȸʒ ǑǬĀ ɍ Āŋ ʔŸʒ ƙŋĀǯĘƺƘǦöä ɃźǪƷ :**General requirement** ÿĀȞöä ǼŸÛǪţä .ǦĀĀǑä gǻĀţä ƂÜ ţźǅÀöĀæ ǦæźÊƮ Û$C_{12}H_{13}ClN_4$ ȸŋ

:**Identity tests** ȟĭǋǈɛ ɩɛþƑǦǁǋɛ

.Dȿ Cȿ B ğäøÅĢǪǹɍä ȿǗ Dȿ A ȸÅøÅĢǪǹɍä ÅȵǗ ĘĚĢÛǨ ȸÒƺ •

Spectrophotometry in ŏäÀȶΣä ǨƠ ĞŐÛÅʈä Ž ɄəƺȒöä ƵĚÛöä âÅĚȩ" ɉäƺÅȝ ǨƠ ȣƺȍƺʈä øÅĢǪǹɍä ĘĢÛł :A ȸȵ ǰǨÀÅöä ƵĚÛöä ȝȵ ŏäÀȶΣä ǨƠ ǦĦȉɉä îÅÔǪȵä ƵĚù ĘæÀÛǪÅ .(43 ǦĦÀÔöä Û1 ÆŸŎä) "the infrared region .ƙȵÅǯĚƺƘĢŸö ɄĦDZÀʈä ƵĚÛöä ȝȵ ȿǗ RS ƙȵÅǯĚƺƘĢöä

ÆÅȝ ÛVS (ȯ/ȯƺȵ 0.005) ȪÅøƺŸȭȿøÆĚȚä ȐƥŽ Ȫȵ/ŷäÀȡȿÀȮȵ 15 ÂĚȭÀǪæ ȯƺŸȚ îÅÔǪȵä ƵĚù ɃÆĢÅ :B ÅÀÀȣȍǗ ÅĚǵȿ ÅĢÀÀŎǨ ÀǪȵƺȹÅȹ 272 ĞDZƺʈä ȯƺÛæ ÅĚȶȚȝǗ ÅĚǵ ÛÀǪȵƺȹÅȹ 350ȿ ÀǪȵƺȹÅȹ 230 ƙæ ĞDZƺʈä ȯƺÛæ ¢ǨÆȽÅÎȵ .ɃÀȣȍɉä ǻΣä ÆÅȝ 0.45ȿ ɄȶȚȝɉä ǻΣä ÆÅȝ 0.48 ȴȅ 1 ĢȹÅǺǯæ ĞŐĢù ȜȝîÅȶǪöä ȵŸĢÅ ÜÀǪȵƺȹÅȹ 260 ĞDZƺʈä ȯƺÛæ

R ȪĚǪĚȅɉä ÆÅøÆĚŒǗȿ R ɄDZŸǯöä ȪĚǪĚȅɉä ȐƥȸȵƙÅƺÅÒǪȵƙȶDzǵǰÅÂȵȸȵȪȵ 1 ȟ 0.5 ɃǗ ȣÅȒÅ :C ĞæÅȅø ǰǪǨ ÜŏÅʈä ȸȵȪȵ 25 ɃǗ ȸǹÅÊöä ǰÅÂʈä ǻÈÔł .ĞŐĚȩǻ 30 ǵÆȵ ɄȝƺDZÀöä øÅĚǪöÅæ ȪȶĦÅ ƵǰȮȵ ǨƠ ȸǺÊÅȿ ĞDZȿÂư TS (ȯ/ȟ 750~) ȯƺȹÅǯÅɋä ȸȵȪȵ 4 øæ ǵøƺŸĚöä ǻÅĦǨ ÛŏÅʈÅæ ȪÊȣǨ ÛĜǹÀȵŽ ĞæÅȅÀöä ȝȶθ .ŏÅȒĚæ ÛĞÅøƺŸæ .(ƙȵÅǯĚƺƘæ ȪĚǪĚȅǗ ɄəÅÅȹ-4Û2) °ŷ172 ĞæäÀȩ ÛøÅȚÔȹɍä ĞDZøǻ Ü°ŷ 105 ǵøäÀǵ ĞDZøÆæ ƵÅθȿ ÛŏÅȵȪȵ 6 Ž

ÛŏÅʈÅæ ĞŐÅȶǯöä ȍŸǺǪÊł ÛR ɄəÅʈä Ÿöä ŷƺÅǻƺÔöä ğÅȹƺæÀȭ ȯƺŸȚ ȸȵ ȟ 0.5 ȝȵ ȟ 0.1 (ȪĦÎł) ÆȵÀł :D ğäøÅĢǪǹä" ɉäƺÅȝ ǨƠ ȣƺȍƺʈä A ȪȝÅÅǪöä ɄÛĦÅ ÜTS (ȯ/ȟ 130~) ȪÅÀǪÅöä ȐƥȯƺŸĦȵ ȯÆĦǪÊÅ .ĜǹÀÅȿ .(121 ĞĦÀÔöä Û1 ÆŸŎä) ğäÆÅøƺŸÒŸö ÂĚȶȶȭ "General identification tests ĞȵÅĦöä ȣäÀĦǪȅɍä

.°ŷ 242 – 239 :**Melting range** øÅȚÔȹɍä ȯÅƒ

.ȟ/ȵŸȵ 1.0 ȸȵ ÀǯȭǗ ȆĚö :**Sulfated ash** ǨÅŸÊʈä ǻÅȵÀöä

5.0 ȸȵ ÀǯȭǗ ÆŐÅÅ ɍ Ü°ŷ105 ǵøäÀǵ ĞDZøÆæ ǨæÅȹ ɉäȿ ʔøǪǵ ƵÅƶ :**Loss on drying** ƵĚÀDZǪöÅæ ÆŐÀöä .ȟ/ȵŸȵ

Ȫȵ 0.25 ȣÅȒÅ .ĜǹÀÅȿ ǻȜÅ ÛŏÅʈä ȸȵȪȵ 15 ȝȵ ȟ 0.3 ʔŸȣÅ :**Acidity or alkalinity** ĞÅƺŸŐöä ȿǗ Ğȑƺȶ Σä ȐƥȸȵȪȵ 0.1 ȸȵ ÀǯȭǗ ɃǗ ĞDZÅǵ ȭÅȽ ǨÊĚö .ÀÅȍǗ ɉƺö ǰǪÅÅ ÜĞǵÅĦÀöä ɃǗ TS ȯƺȹÅǯÅǗ/ȪĚǯĚʈä ǵÀƥȸȵ .ÀƥɉäɃǗ ȯƺŸǂä ɉƺö ƘĚȣǪö VS (ȯ/ȯƺȵ 0.05) ȪÅøƺŸȭȿøÆĚȚä

0.20 ȣÅȒÅ ÛR1 ɄDZŸǯöä ȪĚǪĚȅɉä ȐƥȸȵȪȵ 30 Ž ÛĞĚùƺĜȒȵ ĜȹȿÀƺȵ Ûȟ 0.4 ĞæäÀȩ ãäØł :**Assay** ĞÊÅŐʈä ȣƺȍƺȵ ƺȽ ÅȶȭVS (ȯ/ȯƺȵ 0.1) ȪÅøƺŸȭĢöä ȐȶШ ÀÅĦÅȿ ÛÀĦÎȶȭ TS ȯƺȹÅǯÅɋä/ȸÅÆöÅÅĚÒöä ǵÀƥȸȵȪȵ Ȫȭ ùƺÅÒÅ .(142 ĞĦÀÔöä Û1 ÆŸŎä) A ĞŐÀÅÛöä Û"Non-aqueous titration ɄəÅʈä ɍ ÜȅƺöäŽ ǵÀÅĦʈä" ɉäƺÅȝ ǨƠ .$C_{12}H_{13}ClN_4$ ȸȵ ȵŸȵ 24.87 VS (ȯ/ȯƺȵ 0.1) ȪÅøƺŸȭĢöä Ȑƥ ȸȵ Ȫȵ 1

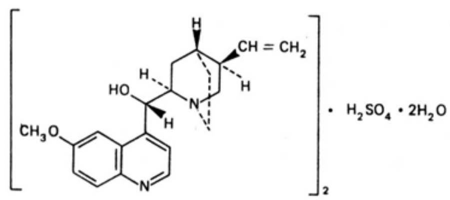
QUINIDINI SULFAS

Quinidine sulfate [illegible]

$(C_{20}H_{24}N_2O_2)_2,H_2SO_4,2H_2O$:**Molecular formula** [illegible]

783.0 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

Quinidine sulfate (2:1) (salt), dihydrate; (9*S*)-6′-methoxycinchonan-9-ol sulfate (2:1) (salt), monohydrate; CAS Reg. No. 6591-63-5 (dihydrate).

[illegible] :**Description** [illegible]

[illegible] TS [illegible] (~750) [illegible] :**Solubility** [illegible]
R [illegible] R [illegible].

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

[illegible] :**Additional information** [illegible]

REQUIREMENTS [illegible]

[illegible] %99.0 [illegible] :**General requirement** [illegible] %101.0 [illegible] $C_{20}H_{24}N_2O_2)_2,H_2SO_4$ [illegible].

:**Identity tests** [illegible]

[illegible] .(B [illegible]) [illegible] 10 [illegible] 0.10 [illegible] :A

.ɋãä ȧøäǚ Ęöüǩ ǰǪĀĀ ÜŌŋ 5 Бǘ ŏȦţȦæ ȤȦƸȿ ÛTS (ȯ/ȟ 100~) ȪĀøȤȦŸÊöä ȒƥʤŋǧäÀÛę ģǼȝ Ōŋ 1.0 Бǘ
ʤŋ Ōŋ 1.0ȿ TS1 ÿȿƎöä ȯȤŸȚ ʤŋ Ōŋ 0.15ȿ ŏȦŋ Ōŋ 4 ÛA øȦǴǪǹŸö ȦȒǂä ȯȤŸǂä ʤŋ Ōŋ 1.0 Бǘ ȣȦȒĀ :B
.ɃåȦŋä ȦȒǹǘ ȷȤö ǰǪĀĀ ÜTS (ȯ/ȟ 100~) ȦƐȹȤŋɉä ȯȤŸȚ

åȤȞæ ōȦȝȿ ÛTS (ȯ/ȟ 40) ǴȒȦöä ǧäÀǪȹ ȯȤŸȚ ʤŋ Ōŋ 1 ȣȦȒĀ ÛåƎĀ ÛʤǹȦȅ ŏȦŋ Ōŋ 5 Ž ȟ 0.05 ǡäØĀ :C
.TS (ȯ/ȟ 130~) ȪĀÀǪÀöä ȒƥŽ ǴäȿæÛĘȧȦęå ģǼȝ ǼȞæ ŏȦȒƐæ ǴǴȅäø ǰǪǨǩ ÜɄǅȦǅȤä

General ǴŋȦȞöä ȣäÀȞǪȅɍä ǧäøȦǴǪǹä" ȷäȤȦȝ ǨƠ ȣȤȍȤɉä A ŌȝȦȦǪöä Ōŋ/ŋŸŋ 20 ȦƐȭÀǪæ ȯȤŸȚ ɄÛȞĀ :D
.(123 ǴɄȦÔöä Û1 ǼŸŎä) ǧȦȦŸÊŸö ȦƐʈʈȭ "identification tests

ȒƥŽ Ōŋ/ŋŸŋ 20 ȦƐȭÀǪæ ȯȤŸȚ ÿǼǺǪÊĀ :**Specific optical rotation** ɄȝȤȦöä ɃÀÔǴöä ÀĀȿǼǪöä
.$[a]_D^{20°C}$ = + 275 to + 290° ǗǴȦȦŎä ģåȦţä Бǘ ţȤǅȤÀȦöȦæ ǼÊȝ ȿ VS (ȯ/ȯȤŋ 0.1) ȪĀøȤŸȭȿøǼƐTä

ȪĀøȤŸȭȿøǼƐTä Ȓƥʤŋ Ōŋ 10 Ž ȟ 0.20 ǡäØĀ :**Clarity and colour of solution** ȯȤŸǂä ȷȤö ȿ ŏȦȦÔöä
ȤȽ Ȧʈȭ ȦʈȚǪȹøȦŌŋ ǼĀȝ Yw2 ɃøȦƐȞţä ȯȤŸǂä ȷȤö ʤŋ ǼȉǗ ȹȤö ȷȤȮĀ ɍ ȿ ǨȤȦȍ ȯȤŸǂä ȷȤȮĀ ÜVS (ȯ/ȯȤŋ 0.1)
.(53 ǴɄȦÔöä Û1 ǼŸŎä) "Colour of liquids ŌöäȤÊöä ȷȤö" ȷäȤȦȝ ǨƠ ȣȤȍȤŋ

.ȟ/ŋŸŋ 1 ʤŋ ȦǯȭǗ ȄƐö :**Sulfated ash** ǨȦŸÊţä åȦŋȦöä

30 ʤŋ ŌęǗ ȄƐö ǼŌȦĀ Ü°ÿ 130 ģøäȦǵ ǴǅøǼæ ǨäȦǯöä ȷäȤöä Ǵǵ Ȥȧƶ :**Loss on drying** ȤƐȦǅǪöȦæ ǼŌȦöä
.ȟ/ŋŸŋ 50 ʤŋ ȦǯȭǗ ȄƐö ȿ ȟ/ŋŸŋ

.6.8 - 6.0 ÛR ȷȤäȦȮöä ǼƐÊȭǗ ɄȧȦȹ ʤŋ ȯȦǹ ŏȦŋ Ž Ōŋ/ŋŸŋ 10 ȦƐȭÀǪæ ȯȤŸȚ ŏȦȽȦæ :**pH Value** ŏȦȽȦǴöä Ǵʈƒę

ǴŌƐęȦöä ǴǴÛöä ǡäÀÎǪȅä" ȷäȤȦȝ ǨƠ ȣȤȍȤŋ ȤȽ Ȧʈȭ øȦǴǪǹɍä ĘǴÛĀ :**Related substances** ǴŏȦÎţä åäȤţä
ǴŸȣŋ ģåȦʈȭ R1 silica gel ȦÒƐŸÊöä ǴŋŸȽ ÿäǼǺǪȅȦæ (84 ǴɄȦÔöä Û1 ǼŸŎä) "Thin-layer chromatography
øȤÛȭ R ƙŋŸƐǯĀǗ ɄȧȦȹ ȯȤŸȚ ʤŋ ÿȤǅǵ 5ȿ ÛR Ƙǫɉä ʤŋ ȦʈǅǵǗ 12ȿ ÛR ʤĀȤȯȤÛöä ʤŋ ȦʈǅǵǗ 20 ʤŋ ǰĀÂŋȿ
øȦǴǪǹɍä ģåȦŋ ʤŋ ŋŸŋ 10 (A) ɃȤȝ :R ȯȤȹȦǯţä Ž ŌƐȦȚ 4 ʤŋ ÀǪȿÀȮŋ 4 ǴɄƐȦÔöä ȜŸȝ ŸÔȦȦŋ ĘǴÛɫ .ȭÀɄǪŋ
ģåȦŋ ʤŋ ŋŸŋ 10 (D)ȿ ÀǪö ɄŸƐţä Ž R ƙȹȤȮȦƐÊöä ʤŋ ŋŸŋ 0.25 (C)ȿ ÀǪö ɄŸƐţä Ž R ƙȦƐȮöä ʤŋ ŋŸŋ 0.25 (B)ȿ
15 ģǼŋ ŏäȤȽ øȦƐǩ Ž ȤǅȤǪö ȭÀǪǩ Ûǡäǡ ÀÎǪȅɍä ģÀǅǵ ʤŋ ǴɄƐȦÔöä ţȦȹ ǼȞæ .C ȯȤŸǂä ʤŋ Ōŋ 1 Ž ǴäØţä øȦǴǪǹɍä
ȯȤŸɄŋ æȦǩ ÛåƎǪö ȭÀǪǩȿ ÛǴŌƐęå 30 ģǼŋ °ÿ 105 ǴǅøǼæ ǴɄƐȦÔöä ʤǺÊǩ .development ƘȚŢǪöä åȦȞĀȿ ǴŌƐęå
ʤŋ ȦȚƐŸȝ ŌÔɄǪÊĀ ǴȞŌæ ǴĀǗ ȷȤȮǩ ɍ .øȦȚȦöä ŏȤȓ Ž ŸäÀÎǪȅɍä ǙÛÅţä ȪɄȦĀȿ ÛTS ÿȤƐȅȦǩȤǴöä ǧȦƐǩŸæȿåȤĀ
ŌʈȭǗ ȷǗ Ǽƶ .C ȯȤŸǂä ȿǗ B ȯȤŸǂä ʤŋ ȦȚƐŸȝ ŌÔɄǪÊĀ Ɣöä ǴȞŌǴöä ʤŋ ģǼȉ ȦǯȭǗ ÛǴƐÊƐȧÀöä ǴȞŌǴöä Ƙȡ ÛǴA ȯȤŸǂä
ŸäÀÎǪȅɍä ǙÛÅţä ȦȚȿǗ äæǗ ɍǗ ȦȤȿǼÔŋ øȦǴǪǹɍä ȷȤȮĀ ɍ .ģȦȉȦǴŋ ǴƐÊƐȧÀöä ǴȞŌǴöä ǨƠ A ȯȤŸǂä ʤȝ ǰǪǨ ǴȞŌæ ǴĀǗ
.ʤȤȓȤæ ƙǪȤȤÔȦŋ ƙǪȞŌæ D ȯȤŸǂä ʤŋ ǰǩȦȦöä

[illegible] 20 [illegible] 0.2 [illegible] :**Limit of dihydroquinidine** [illegible]

[illegible] 0.1 [illegible] TS [illegible] 70~) [illegible] 15 [illegible] R [illegible] 0.5 [illegible]

[illegible] VS [illegible] 0.0167) [illegible] TS [illegible]

[illegible] 5 [illegible] 200 [illegible] 0.5 [illegible]

[illegible] VS [illegible] 0.1~) [illegible] excess [illegible]

[illegible] TS [illegible] 2

[illegible] $(C_{20}H_{24}N_2O_2)_2,H_2SO_4$ [illegible] 18.67 VS [illegible] 0.0167)

[illegible] %15 [illegible]

[illegible] 20 R [illegible] 10 [illegible] 0.20 [illegible] :**Assay** [illegible]

[illegible] VS [illegible] 0.1) [illegible] R [illegible]

[illegible] Non-aqueous titration [illegible] potentiometrically

[illegible] 24.90 [illegible] VS [illegible] 0.1) [illegible] 1 [illegible] (142 [illegible] 1 [illegible]) A

$(C_{20}H_{24}N_2O_2)_2,H_2SO_4$.

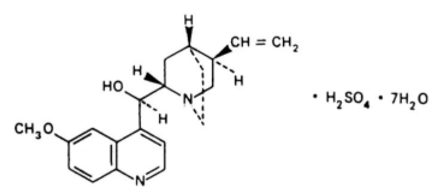
QUININI BISULFAS

Quinine bisulfate [illegible]

$C_{20}H_{24}N_2O_2,H_2SO_4,7H_2O$:**Molecular formula** [illegible]

548.6 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

Quinine sulfate (1:1) (salt), heptahydrate;
(8α*S*,9*R*)-6′-methoxycinchonan-9-ol sulfate (1:1) (salt), heptahydrate;
(8*S*,9*R*)-9-hydroxy-6′-methoxycinchonan sulfate (1:1) (salt), heptahydrate; CAS Reg. No. 6183-68-2 (heptahydrate).

.ǦĦǝǟÀöä ƇƐȝ ÜɹⱬŸöä ȀƐæǕ ÛɃǿⱬŸæ ȧⱬĦÊɳ ȿǕ ɹⱬŸöä ǦƹƐȝ ǧǟǿⱬŸæ :**Description** Ȥòⱬöä

.TS (ȯ/ȟ750~) ȯⱬφǮɋǟ Ž ɹǞȿǾöä ǴƐĦì ÜöǞţǟ Ž ɹǞȿǾöä Ǟǵ :**Solubility** ǦƐφǞȿǾöä

.ǞǿŸţǟ ǻǞȒɳ öǟȿǻ :**Category** ǦǞǞöä

.öⱬȒöä ȸɳ ǦǞţȚ ÛǞƐƉǅ ǦǑŸȣɳ ǦȿǞǵ Ž ƙƐǑöä ǧǞŸÊƐæ ȘǞȝ ɹǕ Ǽƻ :**Storage** ȸǞÂǺǬöä

ǬǿƐǬǩ .ȣǞƨǟ öǟⱬȚǟ Ž ƙƐǑöä ǧǞŸÊƐæ effloresce ǞȽÂǬǩ :**Additional information** ǦƐⱬǞȑǕ ǧǞɳⱬŸĦɳ

.ǦǞǨǞţǟ ǥǿǟÀƩǟ ǧǞǅǿǻ Ž ţÀèǕ ȬǑǞǬöä ǴǴÔǞȿ ÛöⱬȒöä ǟǞȣæ ʔǿǬǵ ÛǼùÀöä ⱬǅŸö ǞȚȑÀǨ ƐǞȝ ǰǞǿƐǬǞæ

REQUIREMENTS ƘǦħǭƱkdž!ƒ

ȸȝ ƐǞÂǞ ɍȿ %98.5 ȸȝ ȬǬǞ ɍ Ǟɳ ʔŸȝ ƙƐǑöä ǧǞŸÊƐæ ɃⱬǬƠ :**General requirement** ȳǞĦöä ƐŸÛǬţǟ

.ǦǞǞÕǟ ǥǻǞţǟ ɃǕ ţⱬǅÀǞæȿ Û$C_{20}H_{24}N_2O_2,H_2SO_4$ ǿƥ ʔŸȝ ǦæⱬÊȚ ÛǦƐǞǞƤɋǟ ǧǞφǟⱬŸǬöä ȸɳ %101.5

:**Identity tests** ǌɨǋǈǁɛ lɛþƑǶƢɛ

ȧǿàǕ ĘöǞǩ ǰǬǞ ÜTS (ȯ/ȟ100~) ȬǞǿⱬǞŸÊöä Ȑƥ ȸɳ Ȭɳ 0.05 ȣǞȒǞȿ öǞɳ Ȭɳ 10 Ž ɳŸɳ 5 ǟǟǾɫ :A

.(B ǿǞǬǹŸö ȯⱬŸǂǟ ȘǞȝ) ƐǞƐì

ÜTS (ȯ/ȟ100~) ǞφⱬɳǰǞ ȯⱬŸȚ ȸɳ Ȭɳ 1.0ȿ TS1 ȳȿƎöä Ȭɳ 0.15 A ǿǞǬǹŸö ÀȒǂǟ ȯⱬŸǂǟ ɃǕ ȣǞȒǞ :B

.ɃǻǞɳä ÀȒǹǕ ɹⱬǞ ǰǬǞ

.öǞȒƐæ ǦæǞèǿ ǰǬǞ ɍ ÜTS (ȯ/ȟ40) ǦȒǞöä ǧǟǞǬφ ȯⱬŸȚ ȸɳ Ȭɳ 1 ȣǞȒǞȿ öǞɳ Ȭɳ 5 Ž ȟ 0.05 ǟǟǾǞ :C

General ǦɳǞĦöä ȣǟǞǬèɍǟ ǧǟǿǞǬǹǟ" ɹǟⱬǞȝ ǨƠ ȣⱬòⱬţǟ A ȬȝǞǞǬöä Ȭɳ/ɳŸɳ 20 ǞƐȭǞǬæ ȯⱬŸȚ ɄÛǞ :D

.(123 ǦĦǞÔöä Û1 ƐŸǑǟ) ǧǞŸÊŸö ǞƐȶȶ "identification tests

Ȑƥ Ž Ȭɳ/ɳŸɳ 30 ǞƐȭÀǞæ ȯⱬŸȚ ȳƐǺǬÊǞ :**Specific optical rotation** ɄȝⱬǞöä ɃÀÔǦöä ÀǞȿƐǬöä

. $[\alpha]_D^{20°C} = -208 \text{ to} - 216°$ ÜǦǞǞǑǟ ǥǻǞţǟ ɃǕ ţⱬǅÀǞǞæ ƐÊȝȿ VS (ȯ/ȯⱬɳ 0.1) ȬǞǿⱬŸȭȿǿƐƐȚǟ

ȬǞǿⱬŸȭȿǿƐƐȚǟ Ȑƥ ȸɳ Ȭɳ 10 Ž ȟ 0.20 ǟǟǾǞ :**Clarity and colour of solution** ȯⱬŸǂǟ ɹⱬǬȿ öǞǞÔöä

ⱬȽ ǞȶȭǞȶȚǬφǿǞǬɳ ƐǞȝ Yw2 ɃǿǞĦţǟ ȯⱬŸǂǟ ɹⱬǬ ȸɳ ƐìǕ ȼφⱬǬ ɹⱬǑǞ ɍȿ ǞƐⱬǞò ȯⱬŸǂǟ ɹⱬǑǞ ÜVS (ȯ/ȯⱬɳ 0.1)

.(53 ǦĦǞÔöä Û1 ƐŸǑǟ) "Colour of liquids ȬǝǟⱬÊöä ɹⱬǬ" ɹǟⱬǞȝ ǨƠ ȣⱬòⱬɳ

.ȟ/ɳŸɳ 1.0 ȸɳ ÀǮȭǕ ÈƐǬ :**Sulfated ash** ǨǞŸÊţǟ ǻǞɳÀöä

0.6 àȿǞǅⱬǬǞ ɍ) ȐǞǺǞɳ Ȁȣȑ ǨƠ ȳ 60 ǥǿǟǞǵ ǦǅǿƐæ Ȥǟƶ :**Loss on drying** ȤƐǞǅⱬǬǞǞæ ƐȬǞöä

.ȟ/ɳŸɳ 240 ȸȝ ƐǞÂǞ ɍȿ ȟ/ɳŸɳ 190 ȸȝ ƐȬǞöä ȬȬǞ ɍ ÜǦȝǞè 18 ǥƐɳ (ǞǦǞÀǬǩ ɄȬǦǝä ȽŸɳ 5 ȿǕ ȯǞǑèǞæⱬŸƐȭ

.3.4 -2.8 10 **:pH Value**

:Related cinchona alkaloids R1 (84 1) "Thin-layer chromatography" R 5 R 12 R 20 10 (A) :R 4 4 10 (D) R 0.25 (C) R 0.25 (B) .C 1 105 °C 30 .development 15 .TS B .C A A .D

:Limit of dihydroquinine 20 0.2 0.5 0.1 15 (~70) TS (v/v 0.0167) .TS 5 200 0.5 2 (v/v 0.1) 21.13 (v/v 0.0167) TS $C_{20}H_{24}N_2O_2,H_2SO_4$.%10

:Assay 25 15 0.45 .R 25 (v/v 0.1) R 20 .R1 50 "Non-aqueous titration" (v/v 0.1) 21.13 (v/v 0.1) 1 .(142 1) A .$C_{20}H_{24}N_2O_2,H_2SO_4$

ØØØØØ

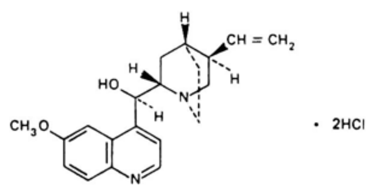
QUININI DIHYDROCHLORIDUM

Quinine dihydrochloride Ďĭďĭ׀׀ε ƍĭϸǊǂ׀ǋβƍĭǉ Ĭ∂Ƒďƙ

$C_{20}H_{24}N_2O_2,2HCl$:**Molecular formula** ǦÆÂƨ Ǧ8ÆÔöä

397.3 :**Relative molecular mass** ǦÆĜÊÂöä ǦÆÂƨä ǦŸǪÒöä

:**Graphic formula** ǦÆφÆĜţä Ǧ8ÆÔöä



:**Chemical name** ȣ∂ÆȶÆÒöä ǈèɍä

(8α*S*,9*R*)-6′-Methoxycinchonan-9-ol dihydrochloride; (8*S*,9*R*)-9-hydroxy-6′-methoxycinchonan dihydrochloride; CAS Reg. No. 60-93-5.

.ǦĦəäÂöä ĈÆɜ ÜĦĜÂÕǩ ȐÆæÜ şÜ ɉζŸöä ȐÆæÜ ÛɃóζŸæ ȧζĦÊɳ :**Description** Ȥòζöä

(ò/ȟ750~) ȯζφÅǯÂɋä Ž āäşæ ɟ ÜR ÿóζζşóζŸÒöä Ž ɉÅæşØöä Àǵ ÜöÅţä Ž ÆÆǅ āäşæ :**Solubility** ǦÆφÅæşØöä

.R ƘǭɉäŽ ÆÆŸȶɜ āäşæ ɟ ÜTS

.ÅÂóɎȶŸö åÅȒɳ öäşå :**Category** ǦÅÀöä

.öζȒöä ȸɳ ɁȶĦɫ ɉÜş ÛÆÆǅ ǦŐŸ8ɳ ǦÂşÅǵ Ž ƘÆÒöä ÆÂóζŸÕşóÆÆȽ ȣ∂ÅǭȘÅʒ ɉÜ Æƻ :**Storage** ȸÂÂǺǭöä

ôÀĤǭöä ÆÂɜ ÆÅÀòÜ ƘÆÒöä ÆÂóζŸÕşóÆÆȽ ȣ∂ÅǭɉζöǴǤÔÂ :**Additional information** ǦÆζÅȑÜ ǧÅɳζŸĦɳ

ǥóäÀΣä ǧÅǅóå Ž ţÀèÜ ȪÒÅǭöä ǴǤÔÂş ÛöζȒöä āÆ8æ ɁøǭǴ ÛÆùÀöä ζǅŸö ȼȑÀĤǩ ÆÂɜ ǰÂóÆǭÅæ ȭøÆǪÂ .öζȒŸö

.ǦĤÅǩÀţä

REQUIREMENTS ƘǦǖǮƙďž!ƒ

ÆÂÂ ɟş %99.0 ȸɜ ŌŎÂ ɟ Åɳ ɁŸɜ ƘÆÒöä ÆÂóζŸÕşóÆÆȽ ȣ∂ÅǭɃζǪƷ :**General requirement** ÿÅĤöä ÆŸÛǪţä

[illegible] %101.0 [illegible] $C_{20}H_{24}N_2O_2,2HCl$ [illegible].

Identity tests [illegible]:

A: [illegible] 5 [illegible] 10 [illegible] 0.05 [illegible] (~100[illegible]) TS [illegible] (B [illegible]).

B: [illegible] A [illegible] 0.15 [illegible] TS1 [illegible] 1.0 [illegible] (~100[illegible]) TS [illegible].

C: [illegible] 0.05 [illegible] 5 [illegible] 1 [illegible] (40[illegible]) TS [illegible].

D: [illegible] 20 [illegible] A [illegible] General [illegible] "identification tests [illegible] (1 [illegible] 121).

Specific optical rotation [illegible] 30 [illegible] (0.1 [illegible]) VS [illegible] $[a]_D^{20C} = -223$ to $-299°$ [illegible].

Clarity and colour of solution [illegible] 0.20 [illegible] 10 [illegible] (0.1 [illegible]) VS [illegible] Yw2 [illegible] "Colour of liquids [illegible]" (1 [illegible] 53).

Sulfated ash [illegible] 1.0 [illegible].

Loss on drying [illegible] 105 [illegible] 30 [illegible].

pH Value [illegible] 30 [illegible] 2.0-3.0.

Related cinchona alkaloids [illegible] "Thin-layer chromatography [illegible]" (1 [illegible] 84) [illegible] R1 [illegible] 20 [illegible] R [illegible] 12 [illegible] R [illegible] 5 [illegible] R [illegible] 10 [illegible] (A) [illegible] 4 [illegible] 4 [illegible] R [illegible] (B) 0.25 [illegible] R [illegible] (C) 0.25 [illegible] R [illegible] (D) 10 [illegible] C [illegible] 1 [illegible] 15 [illegible] development [illegible] 105 [illegible] 30 [illegible] TS [illegible].

Limit of dihydroquinine 0.2 ... 20 ... 0.1 ... 70 ... 15 ... 0.5 ... 0.0167 ... 5 ... 200 ... 0.5 ... 2 ... 0.1 ... 0.0167 ... 1 ... $C_{20}H_{24}N_2O_2,2HCl$ 19.87 ... %10.

Assay 0.3 ... 50 ... 20 ... 10 ... Non-aqueous titration ... 0.1 ... 1 ... (142 ... 1) ... $C_{20}H_{24}N_2O_2,2HCl$ 19.87.

Additional Requirements for Quinine dihydrochloride for parenteral use

"*Parenteral preparations*" (56 ... 4).

ØØØØØ

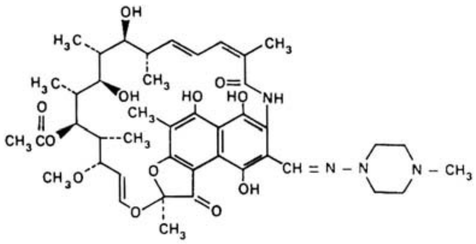
RIFAMPICINUM

Rifampicin

Molecular formula: $C_{43}H_{58}N_4O_{12}$

Relative molecular mass: 823.0

Graphic formula:



Chemical name [illegible]:

(2*S*,12*Z*,14*E*,16*S*,17*S*,18*R*,19*R*,20*R*,21*S*,22*S*,23*S*,24*E*)-5,6,9,17,19,21-Hexahydroxy-23-methoxy-2,4,12,16,18,20,22-heptamethyl-8-[*N*-(4-methyl-1-piperazinyl)formimidoyl]-2,7-(epoxypentadeca[1,11,13]-trienimino)naphtho[2,1-*b*]-furan-1,11-(2*H*)-dione, 21-acetate; 3-[[(4-methyl-1-piperazinyl)imino]methyl]rifamycin; CAS Reg. No. 13292-46-1.

Other name [illegible]: [illegible] Rifampin.

Description [illegible]: [illegible] brick red [illegible].

Solubility [illegible]: [illegible] (~750) [illegible] R.

Category [illegible]: [illegible].

Storage [illegible]: [illegible] 15 °[illegible] 30 °[illegible].

REQUIREMENTS [illegible]

General requirement [illegible]: [illegible] 97.0% [illegible] 102.0% [illegible] $C_{43}H_{58}N_4O_{12}$ [illegible].

Identity tests [illegible]:

A: [illegible] Spectrophotometry in the infrared region" ([illegible] 43) [illegible] RS [illegible].

B: [illegible] 50 [illegible] 50 [illegible] R [illegible] 1 [illegible] 50 [illegible]

4 ÛÀǪƞȤǾǪ 500ȿ ÀǪƞȤǾǪ 220 ƙǽ ǦDZȤƞ ȯȤÛǽ ȼǨƚÎƞ ǼȝӠ ÛǰǨȝ ȯȤŸǂǟ îÔǪƞǟ ȤƗù ɃǼǤ .TS Û7.4 ŏƚǽ
Ǝȝ î ȶǪǟ ǤȶȨ ǤǤÊǪ ƞŸǤǨ ÜÀǪƞȤǾǪ 475ȿ ÀǪƞȤǾǪ 334ȿ ÀǪƞȤǾǪ 254ȿ ÀǪƞȤǾǪ 237 ǦDZȤʈǟ ȯǟȤùÙ Ǽȝ ǦƗȶŢȝÙ ǻȿǼǵ
ǦDZȤʈǟ ȯȤÛǽ ɄȶŢȝɉǟ ɆΣǟ Ǽȝ ǦΘȝǟ ÕŸǨ ƂÙ ÀǪƞȤǾǪ 334 ǦDZȤʈǟ ȯȤÛǽ ɄȶŢȝɉǟ ɆΣǟ Ǽȝ ǈè 1 ǦǾÅǯǽ ǦÕǤù
.ǦǤÀÕǨ 1.75 ÀǪƞȤǾǪ 475

ğÀŸèƘǽ ȡƞ Ōƞ 1 ǦǵÌÀǟ ȡƞ Ōƞ 5 ƂÙ ȣȒR .ǴìÀȿ Ȩǝȩǻ 5 ǥǼƞ ǯÀ ÛǒƞŌƞ 25 Ž ƞŸƞ 25 ȨǨ :C
ƂÙ ǡøȒRǟ Àƥɉǟ ƂÙ ƂÕǨƎǟ ƂÙ ǡøȒRǟ ÀÀòɉǟ ȡƞ ȷȤŸǟ Ƙ8Ǫ ÜȨǝȩǻ ǥƷ ǯÀȿ TS ğÀÊÀǟ Ǧǝøǟǻ/ÿȤƗǪȤƞɉǟ
.ǦǽèǾ ÕÒÎǨ ȷȿǻ ɄDzÊÀǤǟ

ğÀŸè ȯȤŸȚ ȡƞ Ōƞ 4 Ȝƞ ǯÂȿ ÀÒƗŸÊǟ ȡƞ ǦÕǨȤǽ Ž ȟ 1.0 Ȝȑ̀ȤÀ :**Heavy metals** ǦŸƗÕǯǟ ȷǻǨʈǟ
ƂÙ ǦǽøȒ ȿÙ ǒȒRƗǽ ǦǒÀǪ ȝÕǤǨ ȝøǪǵ ƙǺÊǪǟ ȶǪÊȿ ƗƞÀǪǟ ƂÙ øǾŪ ȡɄÊÀ .TS ÕÀøȤŸÊǟ Ȓƥ/ÿȤÀƗ8ʈǟ
ğǟÛȩ ǦȒRǤǽ ǦǽȶǯǞ ɁɆȿ ÛǻƎǪǞ ǾÀǪǨ Û°ÿ 800 ȡȜ ǼÀǨ ɍ ǥøǟǵ ǦDZøǼǽ (ŌȞÎÀ) ƗƞÀ .ÀƗÕǨ ƗȞÙ ʔŸȜ ɃǻƞÀǟ
Ȓƥ Ž ǦǽȶǯǞ ǡǟøǨ ÛÕǽ ƗȞǽ .ǻƎǪǞ ǦǽȶǯǞ ǾÀǪȿ ÛǤƗǪǾǪ ǥÀƞ ƗƞÀ ÛÀǺǤ ÛTS (ȯ/ȟ100~) ÕÀøȤŸÊǟ Ȓƥ ȡƞ
ǴǤÔÀ ʔøǪǵ ÛPbTS (ȯ/ȟ100~) ǾǪȤƞɉǟ ȡƞ ȯȤŸȚ ÛǥÀÛȩ ÀǪÙ ǥÀÛȩ Û8ȒRÀ ÛTS (ȯ/ȟ70~) ÕÀøȤŸǾȿøƗƬǟ
ǴǤÔÀ ʔøǪǵ PbTS TS (ȯ/ȟ60~) ÕǪƗèɉǟ Ȓƥ ÛȒRÀÙ ǥÀÛȩ ÀǪÙ ǥÀÛȩ Û8ȒRÀ Ż Û8.5ȿ 8 ƙǽ ȯȤŸǂǟ ŏƚǽ
ǨƠ 8ȤòȤƞ ȤȽ ȶǾ ǦŸƗÕǯǟ ȷǻǨʈǟ ȡƞ ɁȤǪǂǟ ȡǨÀ .ǯÂȿ ÛŌƞ 40 ƂÙ ŏʈǽ ȤȦ ÛǴǽÌÀ Û4.0-3.0 ŏƚǤǟ
ǦɄÔǟ Û1 ƗŸǑǟ) A ǦÕÀÛŸǾ ǾȤȿ "Limit test for heavy metals ǦŸƗÕǯǟ ȷǻǨʈǟ ÕDZɉ ɃƗΣǟ øǤǪǹɍǟ" ȷǟȤȜ
.ȟ/ÿǟÀǥȿÀÒƞ 20 àȿDZǪ ɍ Ü(128

.ȟ/ƞŸƞ 1.0 ÀǯǾÙ ÈǦ :**Sulfated ash** ǨÀŸÊʈǟ ǻƞÀǟ

0.6 àȿDZǪ ɍ) ȒÀǺƞ Ü8ȑ ǨƠ ŷ 60 ǥøǟǵ ǦDZøǼǽ Ȥǽ :**Loss on drying** ȤƗDZǪǾǽ ƗÕǟ
.ȟ/ƞŸƞ 10 ȡƞ ÀǯǾÙ ƗÕǟ ȷȤÒÀ ɍ Üğȝè 4 ǥǼƞ (ǦǤÀÕǨ ɄÕǤà ǈŸƞ 5 ȿÙ ȯÒèǽȤŸƗǾ

6.5- ÛȨŸʈǟ ŏƚǽ ÛR ȷȤÀÒǟ ƗƗÊǾÙ ɄǝǪ ȡƞ ƂȠǟ ŏʈǟ ȡƞ Ōƞ 10 Ȝƞ ȟ0.10 ǯÀ :**pH Value** ŏƚǤǟ ǤȶȨ
.4.5

ǦÕȩÀǟ ǦǤÛǟ ǡǟÎǪèǟ" ȷǟȤȜ ǨƠ 8ȤòȤƞ ȤȽ ȶǾ øǤǪǹɍǟ ȨǤÛÀ :**Related substances** ǦǒÎʈǟ ǻǟȤʈǟ
ǦŸ8ƞ ǥǻǾ R1 silica gel ÀÒƗŸÊǟ ǦƞŸȽ ÿǟǺǪèǽ (84 ǦɄÔǟ Û1 ƗŸǑǟ) "Thin-layer chromatography
ȡƞ ǰÀƞ ǾÀɄǪƞ øȤÛǾ ÿǺǪÊÀ .TS Û6.0 ŏƚǽ ğǟǽ ğǟǪÊǟ/ğÀÊÀǟ Ǧǝøǟǻ ÿǟǺǪèǽ slurry Ǧȿǟ ƘȒƠȿ
Ž ÕǾȚ 4 ȡƞ ÀǪȿÒƞ 20 ǦɄÔǟ ʔŸȜ ŸÔÀƞ ȨǤÛ .R ȯȤǾǯʈǟ ȡƞ ȶDZǵ 15ȿ R ÿøȤȤȿøȤŸÒǟ ȡƞ ȶDZǵ 85
SV ƙÊǤƞÀøÕƞøȤȤ-3 ȡƞ ƞŸƞ 0.10 (B)ȿ ÀǪ ɄƗʈǟ Ž øǤǪǹɍǟ ǥǻƞ ȡƞ ƞŸƞ 20 (A) ɃȤƷ :R ÿøȤȤȿøȤŸÒǟ
ɄƗʈǟ Ž øǤǪǹɍǟ ǥǻƞ ȡƞ ƞŸƞ 0.20 (D)ȿ ÀǪ ɄƗʈǟ Ž RS ȷȤƗǾ ƙÊǤƞÀøÕƞ ȡƞ ƞŸƞ 0.30 (C)ȿ ÀǪ ɄƗʈǟ Ž RS

ǒȤȓ Ž ǓøǝǞȀȊǫèɍǞ ǕǕǺţǞ ǸǓȀȿş ǒǞȤȚǞ Ž ȤDzǫǒ ȭȀǫǨ ǕāǞȀȊǫèɍǞ ǥȀDzǵ ȸƞ ǦǓǻȀȎǒǞ ţȂøǫ ǼȞǟ .ȀǫǑ ȰȎǓǫȆɅ ǓøǫǞ ǦǑǓǞ ȸƞ ǥǼì ȀǮǑǕ ǕǦǻȆǼǝȀǞ ǦǑǓǞ ǒȀǮǫèȀǟ ǕA ȯȤǙǂȀǟ ȀȚǙ ȰȎǓǫȆɅ ǦǑǝ ǦǕ ȷȤȮǨ ɍ .øȀȚǞ

ǑǙǨ ȸƞ ǥǼì ȀǮǑǕ A ȯȤǙǂȀǟ ȀȚǙ ȰȎǓǫȆɅ ʔȀǹǕ ǦǑǝ ǦǕ ȷȤȮǨ ɍ ǕǑǝ ʔǙ ǥşǄ .Cş B ȯȤǙǂȀǟ ȀȚǙ .D ȯȤǙǂȀǟ ȀȚǙ ȰȎǓǫȆɅ ǓøǫǞ

2 ȤȦƸ .Ȫƞ 100 ǰǫǼǑ R ȯȤǫȀǮţǞ ȸƞ ǦǻȤȀȭ ǦȶȭŽ ǕǦǻùȤǦȒƞ Ǧǫşàȥƞ ǕȟǞ 0.10 ǦǞǞȀę āǞøł :**Assay** ǦȆǻȀȰţǞ

ȻǼǵ Ž ȴè 1 ǦǫȀǺǮǟ ǰǨȀǑǞ ȯȤǙǂǞ ȋȀǫ āȀȪǻ .TS Ǖ7.4 ǒȀŁȀǟ ǕğȀȀȆȀǑǞ ǦǝøǞǼǟ Ȫƞ 100 Ƃǔ ȯȤǙǂǞ āØŁ ȸƞ Ȫƞ

ȸƞ ʔȤǫǂǞ ǼȆƷ .TS Ǖ7.4 ǒȀŁȀǟ ǕǼŁȀȊȭ ğȀȀȆȀǑǞ ǦǝøǞǻ ȳǞǼǺǫèȀǟ ǕǨǦȀȭǨ ȀǫȠȤǫȀǫ 475 ǦDZȤţǞ ȯȤǕǟ ǓŧȚȝɉǞ .($A_{1\,\mathrm{cm}}^{1\%}=187$) 18.7 ǦȀǹȀȠ ǦŧǼę ȳǞǼǺǫèȀǟ Ǖ$C_{43}H_{58}N_4O_{12}$

øøøøø

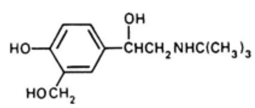
SALBUTAMOLUM

Salbutamol üǋǰǉǂǋǦǁƨǁ

$C_{13}H_{21}NO_3$:**Molecular formula** ǦǻȀǺȀƨǞ ǦȜǻȎǒǞ

239.3 :**Relative molecular mass** ǦǼȆȀǑǞ ǦǻȀǺȀƨǞ ǦǓǫȯǑǞ

:**Graphic formula** ǦǼǫȀǼţǞ ǦȜǻȎǒǞ



:**Chemical name** ǓǝȀǼŧǼȮǑǞ ȴèɍǞ

α[1]-[(*tert*-Butylamino)methyl]-4-hydroxy-*m*-xylene-α,α′-diol;
α[1]-[[(1,1-dimethylethyl)amino]methyl]-4-hydroxy-1,3-benzenedimethanol; CAS Reg. No. 18559-94-9.

.ǦǓǝȀȀǑǞ ȻǼȝ ǕǦǻȀȰǨ ȒǼǞǕ şǕ ȷȤǙǑǞ ȒǼǞǕ ǕɃøȤǙǟ ȧȤǓȆƞ :**Description** ȤȍȤǞ

Ž ȷȀǟşØǑǞ ǴǼǓì ǕTS (ȯ/ȟ750~) ȯȤǫȀǮȀǫǞ Ž āǞşǟ ǕȯȀţǞ ȸƞ ǞȯȂDZ 70 Ž āǞşǟ :**Solubility** ǦǼǫȀǟşØǑǞ .R ǨǫȷǞ

.ȤǟȀǙǒ ǻȀȒƞ ǒǞşǻ :**Category** ǦȀȀǑǞ

.ǒȤȒǑǞ ȸƞ ʔŧȝ ȷǕş ǕǼǻǼDZ ǦǑǙ8ƞ ǦǻşȀǵ Ž ȯȤƞȀǨȤǦȀȆǑǞ ȘȀȝ ȷǕ ǼƵ :**Storage** ȸǻȂǺǫǞ

REQUIREMENTS ƘǦǕǕƱǨǆ!ƒ

%101.0 [illegible] %98 [illegible] :**General requirement** [illegible]
[illegible] $C_{13}H_{21}NO_3$ [illegible].

:**Identity tests** [illegible]

- [illegible] A [illegible] B [illegible] C [illegible] D.

A: [illegible] Spectrophotometry in the infrared region" ([illegible] 43 [illegible] 1) [illegible] RS [illegible].

B: [illegible] 0.080 [illegible] (0.1 [illegible]) VS [illegible] 230 [illegible] 350 [illegible] 276 [illegible] 1 [illegible] 0.56 [illegible].

C: [illegible] 0.05 [illegible] 5 [illegible] 0.1 [illegible] (TS 25[illegible]) [illegible] 0.05 [illegible] R [illegible] (TS ~1760[illegible]) [illegible].

D: [illegible] 155 °[illegible].

:**Sulfated ash** [illegible] 1.0 [illegible].

:**Loss on drying** [illegible] 50 [illegible] 0.6 [illegible] 5 [illegible] 18 [illegible] 5.0 [illegible].

:**Related substances** [illegible] "Thin-layer chromatography" ([illegible] 84 [illegible] 1) [illegible] silica gel R1 [illegible] 4 [illegible] (TS ~260[illegible]) 16 [illegible] 30 [illegible] 2-[illegible] R 50 [illegible] R [illegible] 5 [illegible] R: [illegible] (A) [illegible] 20 [illegible] 0.10 [illegible] (B) [illegible] diazotized TS [illegible] R [illegible] A [illegible] B.

3ŋ ÀĂÅĦĂş R1 ŰĐzŶǯōā ÕĚǪĚèɟā ȐƥȸŋŌŋ 30 Ž ÛĞĚüζĜȒŋ Ǧφşàζŋ Ûȟ 0.4 ĜæāÀę āāØł :**Assay** ĞÊĂÅÕţā

Non-aqueous ŰəÅŋŶōā Ùèζōā Ž ġÀĂÅĦţā" ɹāζÅ3 ĶƠ Ȣζòζŋ ζĿ Åŧõ VS (ȯ/ȯζŋ 0.1) ÕĂøζŶõĶĜōā Ȑŧɯ

23.93 ȕζÅÒĂ VS (ȯ/ȯζŋ 0.1) ÕĂøζŶõşĶĜōā ȐƥȸŋŌŋ 1 Ōõ .(142 ĜĦÅÔōā Û1 ÆŶÕā) A ĞÕĂÀÛōā Ûtitration

.$C_{13}H_{21}NO_3$ ȸŋ ŊŶŋ

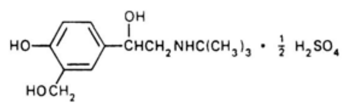
SALBUTAMOLI SULFAS

Salbutamol sulfate üǋǯŽƑŦǋĜǁƑ ƨǁƐ ɭƑƻǂƨ

$(C_{13}H_{21}NO_3)_2, H_2SO_4$:**Molecular formula** ĞĚÅĂÂƨā Ĝ8ĚÔōā

288.4 :**Relative molecular mass** ĞĚĜÊÅōā ĞĚÅĂÂƨā ĜŶǪÒōā

:**Graphic formula** ĞĚφÅĚĜţā Ĝ8ĚÔōā



:**Chemical name** ŰəÅĚŧĚÒōā ɭèɼā

α[1]-[(*tert*-Butylamino)methyl]-4-hydroxy-*m*-xylene-α,α′-diol sulfate (2:1) (salt); α[1]-[[(1,1-dimethylethyl)amino]methyl]-4-hydroxy-1,3-benzenedimethanol sulfate (2:1) (salt); CAS Reg. No. 51022-70-9.

.ĞĦəāÀōā ƇÆ3 ÛĬĜĂÀŌķ ȐĚæÛ şÛ ɹζŶōā ȐĚæÛ ȧζĦÊŋ :**Description** Ȥòζōā

R ŷøζζşøζŶÒōāşTS (ȯ/ȟ750~) ȯζφÅǯĂɋā Ž ɹÅæşØōā ĜĚĦȉ ÜōÅţā ȸŋ ōāÂĐZÛ 4 Ž āāşǽ :**Solubility** ĞĚφÅæşØōā

.R ĶǪɟāş

.ζæÀŶō āÅȒŋ ōāşā :**Category** ĜÅÀōā

.ŏζȒōā ȸŋ ɁŧƷ ɹÛş ÛĬÆĚDZ ĞŌŶ8ŋ ĜĂşÅǵ Ž ȯζŋÅķζĜōÅÊōā ğÅÀŶè ȘÅƷ ɹÛ Ǣƶ :**Storage** ȸĂÂǺǪōā

ÛǢüÀōā ζDzŶō ȼȓÀĦķ ÆĂ3 ǰĂøÆǪōÅæ ȯζŋÅķζĜōÅÊōā ğÅÀŶè õφÆǪĂ :**Additional information** ĞĚζÅȓÛ ğÅŋζŶĦŋ

.ĞĦÅĶÀţā ġøāÀΣā ğÅDZøǻ Ž ţÀèÛ ÕÒÅǪōā ĜĜÔĂş Ûŏζ Ȓōā āÅĚ8æ ɁøǪǵ

REQUIREMENTS ĶĜŀüƱķdž!ƒ

ȸ3 ÆĂÂĂ ɼş %98.0 ȸ3 ŌŌĂ ɼ Åŋ ɁŶ3 ȯζŋÅķζĜōÅÊōā ğÅÀŶè Ƀζǯ3 :**General requirement** ŷÅĦōā ÆŶÛǪţā

.ĜÅÀÕā ġÅÅţā ƂÛ ţζDZÀōÅæ ĜæζÊƮ Û$C_{13}H_{21}NO_3$,½H_2SO_4 ȸŋ %101.0

Identity tests [illegible]:

• [illegible] A [illegible] B، C، D.

A: [illegible] "Spectrophotometry in the infrared region" ([illegible] 43 [illegible]) [illegible] RS [illegible].

B: [illegible] 0.080 [illegible] (0.1 [illegible]) VS [illegible] 230 [illegible] 350 [illegible] 276 [illegible] 1 [illegible] 0.46 [illegible].

C: [illegible] 0.05 [illegible] 5 [illegible] 0.1 [illegible] (25 [illegible]) TS [illegible] 0.05 [illegible] R [illegible] (1760~ [illegible]) TS [illegible].

D: [illegible] 20 [illegible] A [illegible] General "identification tests ([illegible] 1.0 [illegible] 123).

Sulfated ash [illegible]: [illegible] 1.0 [illegible].

Loss on drying [illegible]: [illegible] 100 [illegible] 0.6 [illegible] 5 [illegible] 18 [illegible] 5.0 [illegible].

Related substances [illegible]: [illegible] "Thin-layer chromatography ([illegible] 1 [illegible] 84) [illegible] silica gel R1 [illegible] 4 [illegible] (260~ [illegible]) TS [illegible] 16 [illegible] 30 [illegible] 2-[illegible] R [illegible] 50 [illegible] R [illegible] 5 [illegible] R: (A) [illegible] 20 [illegible] (B) [illegible] 0.10 [illegible] TS diazotized [illegible] A [illegible] B.

Assay [illegible]: [illegible] 0.9 [illegible] 30 [illegible] R1 [illegible] (0.1 [illegible]) VS [illegible] "Non-aqueous titration"

ꝺꞑ ŋŶꞑ 57.67 ừʐẨỎ VS (ỏ/ỏʐꞑ 0.1) ỖẨǿʐŶỗʂƘǴä Ȑ ƥ ꝺꞑ Ỗꞑ 1 Ỗỗ .(142 ǴȞẢÔä Û1 ǼŶǑä) A ǴỖẨÛä

.$C_{13}H_{21}NO_3,½H_2SO_4$

ƒdžsѲ üƒDžyƗƨŰƐ üШǓ üNjDžƑƗNjǴǁƑƨǁƐ lƑ2ƗƨǁhʊǐʒƑȚƋ lƑǴƗƯƗDž

Additional Requirements for Salbutamol sulfate for parenteral use

.(56 ǴȞẢÔä Û4 ǼŶǑä) "*Parenteral preparations* ǴǼẢỖΣä ğẢȒȞǪÊƫä" ģấʂẢʐɉ ǼǼDzǪÊẨ

SENNAE FOLIUM

Senna leaf (ǏǏDžƑdžƨǁƐ) ƑdžƨǁƐ hʊɓNj

Alexandrian Senna leaf hʊǐɓǫdžǀƨŰƐ ƑdžƨǁƐ hʊɓNj

Tinnevelly Senna leaf ǏƗǐ2ǐdžǐƗ ƑdžƨǁƐ hʊɓNj

ẨẨÊä ǴʐʂẢȞƫä ÛǴẢẢǑä *Cassia senna L.* øä ğẢỖẨǿʂ ꝺꞑ ẨẨÊä Ǵȩǿʂ ɹʐỎǪ **:Composition** ǼǼỗẢǪä ꝺꞑ ǰẨÂꞑ ꝺꞑ ʂ Û(*C. angustifolia* Vahl) Tinnevelly Senna ʂ (*C. acutifolia* Delile) ÿʐừẢƪä ʂ ǴẨǿǼẨỎềɋä .ƙɜʐẨä

.ŸŶȩ Ẩꞑ Ż ÛʐŶģʂ mucilaginous ƟẢǯö ǴẨäǼǴä Ž Ûȧäǿƫä ÜǴẢǼẢǹ ÛǴȞǝäẢä **:Description** Ȥòʐä

.ỖŦÊꞑ **:Category** ǴẨẢä

.ǴǽʐừẢäʂ öʐȒä ꝺꞑ ẨẨÊä Ǵȩǿʂ ɁƭƠ ɹ Æʑ **:Storage** ꝺẨÂẤǪä

ɁøǪģ ÛǢừẢä ʐDzŶö ẢŦȑẢȞ ǼẨɜ ǰẨǿǼǪẢä ẨẨÊä Ǵȩǿʂ ỗǿǼǪ **:Additional information** ǴǼʐẢȑ ğẢꞑʐŶȞꞑ .ǴȞẢǨẢƫä ģǿäẢΣä ğẢDzǿấ Ž ƫẢềỖỎẢǪä ǴǴÔẨʂ Ûöʐȓä ā ẨǼ8ä

REQUIREMENTS ƘǴʉǁƱƙdž!ƒ

ƟÊỗʂǿǼǼ ğẢỖǪÎꞑ ꝺꞑ %2.5 ꝺɜ ỖỖẨ ɍ Ẩꞑ ɁŶɜ ẨẨÊä Ǵȩǿʂ ɃʐǪƠ **:General requirement** ÿẢȞä ǼŶÛǪƫä .(sennoside B) B ǼẨäʐǼÊỗ ǴäʐÊȚ Ûƙềäẩǯǫ

:Identity test hʊǐNjNJǁƐ ɓƑǴƗƢƐ

ÿẢƥ Ž Ɂẩ8ẨʂTS ỏʐǫẢǯẨɋä/ÿʐẨấʐÔä ǼǼÊỗʂǿǼǼ ỏʐŶȚ ꝺꞑ Ỗꞑ 10 ǴȩʐȞÊƫä Ǵȩǿʐä ꝺꞑ ȟ0.5 Ƃ 8ẢȒẨ øä ỜŶẤǪÊẨʂTS (ỏ/ȟ70~) ǼẨǿʐŶỗʂǿǼǼŦä ȐƭШ ǴģẢïẢä ȐƫȞɫ .ǴïẢẨʂ ÛǒẢꞑ Ỗꞑ 10 ÿäǼẤǪềẢä ȤẢƩ ÛƟǝẢꞑ Ž ẨẢÔꞑ ẢƥɹʐöǰǪẨÜTS (ỏ/ȟ100~) ẢǼǫʐꞑɉä ỏʐŶȚ ꝺꞑ Ỗꞑ 5 ɜꞑ ɀẢǩʂ Ƙǫɉä ǴỖǴừ ỖỎẢǩ .R Ƙǫɉä ꝺꞑ Ỗꞑ 10 .ẢǼǫʐꞑɉä ǴỖǴừ

:**Macroscopic examination** ȹøφǺĚĦöä ÒĦǺöä

ÜĞǺφúŋ ÛÕÒÎöä ĞĘφǺǺè ÜĞÎŁ ÛĞÕĘęø ÛÆǵǺÎöä ɃǻǺŋǺöä ɃǗ ĞæøǺȓ öäÀŘǹ ǧǺÕǺøş *:ĞǺøÆǺÒèqǟ ǺǺè Ğęøş*
ÜǺŸĘŸę ĞDZζȶϘŋ ÛĞĦĘǺÔöä ÜǺŸĘŸę ÂõÀţä ÕǺèǗ ĞÛÕǺöä ǼǺȝ ȷζÒǩ Ǻŋ ôÀȝǗ ÛĻŸŋ 15-5 Ûô ÀĦöä ÜĻŸŋ 40-20 ÛòζÛöä
ȻøǻǺ8ǩş ǺŸĘŸę àøǺæ Ùèşɉä ȝŸŘöä ÛÕÒÎöä ȹÎǺø ǵǻøşɉä ţàζǩ ÜĞȶȝǺφ ÛǵƘÔę ǧǺǺǺĦÎæ ȷǺĘÛ8ŋ ƙĦÛÊöä Ÿõ
.ĞζǺĦŸö ǺǺàäζŋ ǺζÀǵ ÕÒÎϘ ÀȡǺǺϘǩş ǺĞǺÀÕǩ °ȳ 260 ĞǺşǟǺæ ĞĘφǺƨä ǵǻøşɉä

ôÀĦöä ÜĻŸŋ 50-25 ÛòζÛöä ÜĞǺφúŋ ÛÕÒÎöä ĞĘφǺǺèş ĞöşǺÛϘŋ ÜǵÀǺÔŋ öäÀŘǹ ǧǺÕǺøş *:ȹŸǯ ȹøǺĚǩ ǺǺè Ğęøş*
ȓζÛŅ ĞŋζèζŋȘ ÛǧǺǺǺĦÎöä ȸŋ ǺĚDZ ÕĘŸę ǻǼȝ ȝŋ ƙÊŸŋǗ ƙĦÛÊöä Ÿõ ÜĞĦÛÊŋ ÛĞĦĘǺÔöä ÜĻŸŋ 20-7 ÛÂõÀţä ǼǺȝ
.ĞŸəǺŋ şǗ Ğȓ ÀĦϘÊŋ

(źǺĞǺöä ŋȶÔöä) ÜǯŸöä ɃζƠ ĞĦŸŘŋ ǺǺŸǹ ǧäæ ǵÀÎĞöä :**Microscopic examination** ɃÀȚŎä ÒĦǺöä
ÛǵǼȝǺÕöä ǼǺȝ ǺŸĘŸę ĞĘǺĦǺŋ ÛÀϘŋşÀÒŋ 260 ȥøϘǵ ÛòζÛöä ÛǵƘDZΣä ǵǼĘǵş øäǼƨä ĞǺĘǺϘ ǧǺǺǺĦȉ Ümucilage
ĞǺǻζÕǺȝ ǧäøζŸæ ÜĞÒĘÊǵ ĞÕĞù ȸŋ ǻǺǺŋ ÀÛè ĞǺşÀÎĞöä ǺǺŸƪä ǨƠ ÜƙȚDZζöä ȥŸȝ ĞǺζŸǹ ǼφǺDZ ǧǺŁζζ ÜĞĘöζöúϘ
8ǺĘöǗ ÛøζǂäζǗ ȻDZϘţä ĞęøζöäǴÛè ȥŸȝ ÜǺŸŋǺõ lacunose āȥÕä ȷĘÊǺöä Ž ǵÀÎϘǺŋ ȳζĘÊöǺÒöä ǧɼǺÊõşǗ ȸŋ
ȸŋ ĞǺøζȉζŋ ǧäøζŸæ ȥŸȝ ɃζϘƠ ÂõÀţä ȸȝ ǺĚĦæ ȻDZϘţä ǴÛÊöä ȥŸȝ ĞææǺĘţä ÕÒÎæ ĞöǺÎŋ 8ǺĘöǗ Ğȝζȶƭş Ğȶȝǻǻ
.ȳζĘÊöǺÒöä ǧɼǺÊõşǗ

R ȳøζζşøζŸÒöä ȸŋ Ōŋ 0.5 ȸŋ ȷǺǺŋ Ž ȟ 5 ǦÀǺ :**Water-soluble extractive** öǺţä Ž āäşǾöä ÒŸǺϘÊţä
.ȟ/ŋŸŋ 300 ȸȝ ĞöǺȶǯöä ÕÕǩ ɍ ÜȷàζǺş ĞǵǺȉÀöä ȸŋ Ōŋ 20 ÀǺĞǺ ÛĞŋȉÀǺ ÛöǺŋ Ōŋ 200ş

ǻǺŋÀöä ƙĘĦǩ" ȷäζǼȝ ǨƠ 8ζòζŋ ζŁ Ǻȶõ öäÀDZqä ĘĞÛǺ :**Acid-insoluble ash** ȒȶΣä Ž āäşǾöä Ƙȡ ǻǺŋÀöä
ȸŋ ȸŋ ÀǯõǗ ȷζÒǺ ɍ Ü(173 ĞĦǺÔöä Û1 ǼŸÕä) "Determination of Acid-insoluble ash ȒȶΣä Ž āäşǾöä Ƙȡ
.ȟ/ŋŸŋ 20

ǤÎϘÒǩ .ĞÕĘęø ĞÕĞÛõ ÀÎǺǩş ǺĞǺÀÕǩ ȟ 200 ȷàζǺ :**Stems and foreign matter** ĞĞǺÀ8öä ǵǻǺţäş ţşǾƨä
ÀǯõǗ ǼDZζǺ ɍ ÜĞǻÀǺŋ ǺÕõ ĞĞǺÀ8öä ǵǻǺţäş ţşǾƨä ȷàζǩş ÕÔǺǩ Ü6× ĞèǼȝ ȳäǼǺϘèǺæ şǗ ƙĦöǺæ ĞĞǺÀ8öä ǵǻǺţäş ţşǾƨä
.ĞĞǺÀ8öä ǵǻǺţä ȸŋ ȟ/ŋŸŋ 10 ȸŋ ÀǯõǗ ɍş ţşǾƨä ȸŋ ȟ/ŋŸŋ 20 ȸŋ

ÛǮÂȶł ÛöǺŋ Ōŋ 30.0 8ǺŘǺ .Ōŋ 100 ĞĦè ǧäæ ĞŸDZζǵ Ž ĞęζĦÊţä ȧǻøşɉä ȟ 0.15 ȝȓζł :**Assay** ĞÊǺǺÕţä
õÀϘǺ .ĞÕĘęǻ 15 ǵǼŋ ȹȝζDZÀöä ȷǺǺÀƨǺæ ÕȶĦǺ ǤǯÒŋ ǨƠ ȸǺÊǺ .°ȳ 90-80 ĞDZøǼæ ȹəǺŋ ȳǺƥ Ž ȝȓζǺş ȷàζǺ
ȝȶę ɃǗ ŽǺÛöä ÕəǺÊöä ȸŋ Ōŋ 20.0 ÕÕǺǺş ÕǺǯǺ .ĞĘŸòɉä ĞŸϘÒöä ȥŸȝ òζÔΣä ȥøϘǵ öǺţǺæ ĞĦÔǺş ÛȷàζǺ ÛǻǺĘĘö
Õõ ÛǧǺĘȶõ ǫŸϘ ȝŋ ǯǺǺş TS (ò/ȟ70~) ÕǺøζŸõşøǼĚȚä Ȓƥ òζŸȚ ȸŋ Ōŋ 0.1 8ǺŘǺ .Ōŋ 150 ȝÊϘǺ ÕÔζ
ƙDZşøǼĚŁ ǧǺφζæÀõ ȸŋ ȟ 0.10 8ǺŘǺ .ȳøζζşøζŸÒöä ĞÕĞù ȥŋÀǩş ÕÔǺǺĘö õÀϘǺ .R ȳøζζşøζŸÒöä ȸŋ ÛŌŋ 15 ǺȚǺŋ

[illegible] 10.0 [illegible] 3 [illegible] R [illegible] TS (ò/ȟ65) [illegible] 20 [illegible] 100 [illegible] ground glass [illegible] 20 [illegible] 20 [illegible] TS (ò/ȟ420~) [illegible] 1 [illegible] R [illegible] 25 [illegible] 3 [illegible] 15 [illegible] 10.0 [illegible] .R [illegible] 100 [illegible] .R [illegible] R [illegible] 5 [illegible] 10.0 [illegible] .R [illegible] 515 [illegible] 1 [illegible] 24.0 [illegible] B [illegible] *W* [illegible] 515 [illegible] *A* [illegible] *W/A* 1.25 [illegible] ($A^{1\%}_{1cm} = 240$) [illegible].

ØØØØØ

SENNAE FRUCTUS

Senna fruit [illegible]

Alexandrian Senna fruit [illegible]

Tinnevelly Senna fruit [illegible]

C.) [illegible] *Cassia senna* L. [illegible] :**Composition** [illegible]
.[illegible] *C. angustifolia* Vahl [illegible] (*acutifolia* Delile

.[illegible] mucilaginous [illegible] :**Description** [illegible]

.[illegible] :**Category** [illegible]

.[illegible] :**Storage** [illegible]

[illegible] :**Additional information** [illegible]
.[illegible]

REQUIREMENTS [illegible]

ğ ÅÖ̥Îņ ȸņ %3.4 ȸʒ ÕÕ ɍ Åņ ʡʒ ǦÂøÆÅÒèqā ÅÅè ǦƮÕÅȥ Ƀȥ̥Ơ :**General requirement** ÿÅȞöā ÆÝÛ̥ţā
Ûƙèā ÅǯφÜ ɄÊõşøÆȽ ğ ÅÖ̥Îņ ȸņ %2.2 ȸʒ ÕÕ ɍ Åņ ʡʒ ɄÝÆÅÆǨ ÅÅè ǦƮÕÅȥ Ƀȥ̥Ơş ƙèā ÅǯφÜ ɄÊõşøÆȽ
.B ÆÅäȥÆÊõ āȥÊȚ ÅƵŶõ

:**Identity test** ƕĭǊǇǁ ƥƑǴƢɛ

TS ȯȥφÅǯÅqā/ÿȥÅåȥÔöā ÆȽÊõşøÆȽ ȯȥÝȚ ȸņ Ŏņ 10 8ÅȒÅ Ûȟ 0.5 ǦäāÅę ĘȞÊÅ şÜ ǥƘ8ȍ ÅȞÛę ǦƮÕÅÅöā ʒÛÕǩ
TS (ȯ/ȟ70~) ÆÅøȥÝõşøÆȽTā ȐȶɯɯǦǵÅȉÅöā ȐȶƠ .ǴȉÅÅş ÛöÅņ Ŏņ 10 ÿāÆḀ̊́èÅǣ ȤÅƩ ÛɄǝÅņ ÿÅƥ Ž ʡ8Åş
ǰ̥ÅÅ ÜTS (ȯ/ȟ100~) ÅÆφȥņɉā ȯȥÝȚ ȸņ Ŏņ 5 ʒņ ǯÅǩş ƘǭɉāǦÕǦü ŎÔÅǩ .R ƘǭɉāȸņŎņ 10 øǣ ȌÝḀ̊́ÊÅş
.ÅÆφȥņɉā ǦÕǦü Ž ÅƥÜ ƁÜ ɄÝÅφÅę ɉȥö

ǦÆÅǣ ƁÜ ǥÅÅÔņ öāÅȒȵ ÛǦÕÆęøş ǦȞÛÊņ ÛǦęøȥöā ŎǯņɉşÅę :**Macroscopic examination** ɄøφÅÆȞöā ȌȞÅöā
.ŎȮÎöā ǦÅȥÝõ şÜ ǦÝÆÛ̥Êņ ÛǦÕņÅȡ ǦÆÅǣ ǦÅÂõÅņ ǦÕÛÅņ ʒņ ǥÅÅÔņ

ǦÅÅæqā ǦÛÕÅöā ÜȴÝņ 25-20 Û ȏ ÅȞöā ÜȴÝņ 50-40 ǦäāÅę ÛȯȥÛöā ÜǦÅåÅņø ƁÜ ǦǦǵÅȉ öāÅȒȵ *:ǦÅøÆÅÒèqā ÅÅè ǦƮÕÅȥ*
ǦÆφɍȥü 8āȥǵ ğāǣ ÛǦǦǵÅȉ ǦÆÅǣ ƁÜ öāÅȒȵ obovate āȥÝÕņ ɄȒÆǣ ÅƮÝÒȉ øşØǣ 7-6 Ƀȥ̥Ơ Ûğ ÅÅƮÅöā ʔÆǵÜ ÆÅʒ ǦÅÅæqā
.ǥÅøÅǣ

ǦÛÕÅöā ÜȴÝņ 18-14 Û ȏ ÅȞöā ÜȴÝņ 60-35 ǦäāÅę ÛȯȥÛöā ÜɃåÅņÅöā ƁÜ ǦǣøÅȓ öāåȥè ƁÜ ǦÆÅǣ *:ɄÝÆÅÆǨ ÅÅè ǦęøşÉ*
ğāǣ ÛǦǦǵÅȉ ǦÆÅǣ ƁÜ öāÅȒȵ obovate āȥÝÕņ ɄȒÆǣ ÅƮÝÒȉ øşØǣ 10 ʡø̥ǵ Ƀȥ̥Ơ Ûğ ÅÅƮÅöā ʔÆǵÜ ÆÅʒ ǦÅÅæqā
.åşÆΣā ǦȞȓāş Ƙȡ ǦȓÅȞ̥Êņ 8āȥǵ

øÅÛęɉā ǦÅşÅÊ̥ņ ÅÅŶȵ ȸņ Ȥöü̥ǩ epicarp ǦƊǱøÅȴā ǥÅÎöā :**Microscopic examination** ɃÅƮÕā ȌȞÅöā
ȸņ ÅÆǱ ŎÆÝę åÆʒş ÛÅφÅÆǵÜ *anomocytic* şÜ *paracytic* ÅÅŶǺÝö ǥøşÅƒ ğÅȽȥȥ ʒņ ÛÅÆǱ ǦÆḀ̊́ ğāÆÆÝǱ ğāǣ
ǦÛèȥ̥ţā ǥÅÎöā Ûcollenchymatous ǦÅşÅȡ ÅÅŶȵ ğāǣ *Hypodermis* ǦȶȞÝö ÛǦÆÝȴā ǥÆÆǵş ǦÆöȥöǘǯöā ğÅÅȞÎöā
ȸņ ǦφȥÒņ endocarp ǦÆÝȵāÆöā ǥÅÎöā ÛÿȥÆÊöÅÒöā ğɍÅÊõşÜ Ƙȉāȥņ ȸņ ǦÕǦü Ƀȥ̥ʒ ɄøḀ̊ņ ǰÆÊφ ğāǣ mesocarp
şÜ ǦÝǝÅņ ǦÅşāÅǣ ƘÊǩ ǦÆÝȵāÆöā 8ÅÆöɉā ȸȮö ÛǦƮÕÅÅÝö ɄøφɍȥÛöā øȥɫā ʡʒ ɃåȥȶʒÅƮȶȚȞņ Ž ÛøāÆƨā ǦÆḀ̊́ 8ÅÆöÜ
ÜƙḀ̊́ ɄǱøÅȵ øāÆǱ ğāǣ palisade ǦȮÆÊǵ ÅÅŶȵ ȸņ ǦÅşÅÎǣ ǨƠ ǦÕǦü ÛøşÂǦöā .ɄøφɍȥÛöā øȥȞȶÝö ǦÅäāȥņ
.mucilaginous ǦÆÅǯõ ÅŒāøÆǱ polyhedral ǳȥÛÊöā ǥǨǯõ ÅÅŶȵ ğāǣ endosperm öāÆÅȥÊöā

R ÿøȥȥşøȥÝÒöā ȸņ Ŏņ 0.5 ȸņ ǰÅÅņ Ž ȟ 5 ǯÅÅ :**Water-soluble extractive** öÅţā Ž āāşØöā ȌÝḀ̊́Êţā
.ȟ/ŋÝņ 250 ȸņ ŎęÜ ǨÊÆö ǦöÅȶǯöā ÜɉäȥÅş ǦǵÅȉÅöā ȸņ Ŏņ 20 ÅǺǦ ÛǦȉÅÅ ÛöÅņ Ŏņ 200ş

åÅņÅöā ƙÆȞǩ" ɉāȥÅʒ ǨƠ 8ȥȍȥņ ȥȽ ÅȶõöāÅǱȥqā ĘǦÛÅ :**Acid-insoluble ash** ȐȶΣā Ž āāşØöā Ƙȡ åÅņÅöā

[illegible] (173 [illegible] 1 [illegible]) "Determination of Acid-insoluble ash [illegible] 20 [illegible]

[illegible] 200 [illegible] :**Foreign matter** [illegible] 6× [illegible] 10 [illegible]

[illegible] 0.15 [illegible] :**Assay** [illegible] 100 [illegible] 30.0 [illegible] 90-80 [illegible] 15 [illegible] 20.0 [illegible] 150 [illegible] 0.1 [illegible] TS (70~[illegible]) [illegible] 15 [illegible] 0.10 [illegible] 3 [illegible] 10.0 [illegible] ground glass [illegible] 100 [illegible] 20 [illegible] TS (65[illegible]) [illegible] 20 [illegible] TS (420~[illegible]) [illegible] 20 [illegible] 1 [illegible] 25 [illegible] 3 [illegible] 15 [illegible] 10.0 [illegible] 10.0 [illegible] 100 [illegible] 5 [illegible] 515 [illegible] 1 [illegible] ($A_{1cm}^{1\%} = 240$) 24.0 [illegible] B [illegible] 515 [illegible] W [illegible] A [illegible] W/A 1.25 [illegible]

øøøøø

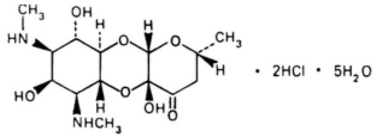
SPECTINOMYCINI HYDROCHLORIDUM

Spectinomycin hydrochloride [illegible]

$C_{14}H_{24}N_2O7,2HCl,5H_2O$:**Molecular formula** [illegible]

495.4 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



[illegible] **:Chemical name**

(2*R*,4a*R*,5a*R*,6*S*,7*S*,8*R*,9*S*,9a*R*,10a*S*)-Decahydro-4a,7,9-trihydroxy-2-methyl-6,8-bis(methylamino)-4*H*-pyrano[2,3-*b*][1,4]benzodioxin-4-one dihydrochloride pentahydrate; [2*R*-(2α,4aβ,5aβ,6β,7β,8β,9α,9aα,10aβ)]-decahydro-4a,7,9-trihydroxy-2-methyl-6,8-bis(methylamino)-4*H*-pyrano[2,3-*b*][1,4] benzodioxin-4-one dihydrochloride pentahydrate; CAS Reg. No. 22189-32-8 (pentahydrate).

.[illegible] **:Description** [illegible]

R [illegible] TS [illegible] (~750) [illegible] **:Solubility** [illegible] .R [illegible]

.[illegible] **:Category** [illegible]

[illegible] **:Storage** [illegible] .°[illegible] 30 [illegible]

REQUIREMENTS [illegible]

600 [illegible] **:General requirement** [illegible] $C_{14}H_{24}N_2O_7$ [illegible].

:Identity tests [illegible]

Spectrophotometry in [illegible] :A "the infrared region [illegible] (43 [illegible] 1 [illegible]). [illegible] RS [illegible].

[illegible] B [illegible] 20 [illegible] 20 [illegible] :B "General identification tests [illegible]" [illegible] (121 [illegible] 1 [illegible]).

ţzǅÀōǻ ÆÊƷş Ōŋ/ŊŸŋ 0.10 ÂĿÕÀǪǽ ȯzŸƬ ÿǼǺǪÊÀ :**Specific optical rotation** ƟʒzÁǟ ƁÀÔǤǟ ÀĮşǼǪǟ
.$[a]_{D}^{20°C} = +15$ to + 21° ÜǦǝÀţǟ ɍ ǵǻţǟ Ɓǚ

.ȟ/ŊŸŋ 10 ȸŋ ÀǰÕǚ ȄĿö :**Sulfated ash** ǨÀŸÊţǟ ǻÁŋÀǟ

Determination of water by ÀÎĿz ȯøÀÕ ǦǑÀÛǽ ǒÀţǟ ƙĿȞ" ȷǟzÁʒ ǨƠ Ȣzòzŋ zĿ Àŧ Õ ȸĿȞÀ :**Water** ǒÀţǟ
ʔzǪƬ ŎÕÀ ɍ ÜǦÀÕǩ ǵǻţǟ ȸŋ ȟ 0.2 ÿǟǼǺǪèÀǽ Û(145 ǦƜÀÔǟ Û1 ǼŸǑǟ) A ǦǑÀÛǟ Û"the Karl Fisher Method
.ȟ/ȟ 0.20 ȸʒ ǼÀÂÀ ɍş ȟ/ȟ 0.16 ȸʒ ǒÀţǟ

.5.6-3.8 ÛŎŋ/ŊŸŋ 0.10 ÂĿÕÀǪǽ ȯzŸƬ ǒÀĿÀǽ :**pH Value** ǒÀĿÀǤǟ Ǧŧ Ŀę

ǦǑǤÛǟ ǟǟÀÎǪèǟ" ȷǟzÁʒ ǨƠ Ȣzòzŋ zĿ Àŋ ÆÊШ øÀǤǪǹɍǟ ʔÀƶ :**Related substances** ǦǒÀÎţǟ ǻǟzţǟ
ǰÀÂŋş ǦŸŸȢŋ ǵǻŧ Õ R1 ÀǑĿŸĿÊǟ ǦŋƳĿ ÿǟǼǺǪèÀǽ Û(84 ǦƜÀÔǟ Û1 ǼŸǑǟ) "Thin-layer chromatography ǦǑĿęÀǟ
ȸŋ Ǽǵǟş ǈǅǵş R ƟǅzŸǰǟ ŌĿǪĿèȷǟ Ȑ Ƿ ȸŋ Ǽǵǟş ǈǅǵş ǒÀţǟ ȸŋ ÿzǅǵ Ȣş R ȯzǪÀǽşÀǽ-1 ȸŋ ÿzǅǵ 10 ȸŋ
ǵǻŋ ȸŋ ŊŸŋ 20 (A) Ɓzʒ :ƙǒzŸƬ ȸŋ ÀǪǒşÀǑŋ 10 ǦƜĿÀÔǟ ʔŸʒ ŸÔÀÂŋ ĘǤÛŀ .ŌÀƜǪŋ øzÛ Õ R ȸÀǼÀƘǤǟ
Ûǟǟ ÀÎǪèɍǟ ǵÀǅǵ ȸŋ ǦƜĿÀÔǟ ţÂøǫ ǼȞǽ .ÀǪǒ ƟŸĿţǟ Ž øÀǤǪǹɍǟ ǵǻŋ ȸŋ ŊŸŋ 0.20 (B)ş ÀǪǒ ƟŸĿţǟ Ž øÀǤǪǹɍǟ
ȌƜÀĮş ÛĘǝÀęǻ 3-2 ǵǼŋ ÀǑǪÊǪǒ ŌÀǪǩ ÛTS (ȯ/ȟ25) ÿzĿèÀǩzǤǟ ǧÀǫÀȢÀŋƘǽ ȯzŸƜŋ ǽÀǩ ÛǒǟzƬǟ Ž ƵǅzǪǒ ŌÀǪǩ
ÀǰÕǚ ÛǦĿÊĿǝÀǟ ǦȞǤǟ ǒÀǰǪèÀǽ ÛA ȯzŸŧ Àǽ ÀƵĿŸʒ ŎÔƜǪÊÀ ǦȞǽ ǦǙ ȷzǑǩ ɍ .øÀƵÀǟ ǒzȑ Ž ƟøǟÀÎǪèɍǟ ȔÛǺţǟ
.B ȯzŸŧ Àǽ ÀƵĿŸʒ ŎÔƜǪÊÀ ƟøǪǟ ǦȞǤǟ ȸŋ ǵǼȉ

øÀǤǪǹǟ" ȷǟzÁʒ ǨƠ Ȣzòzŋ zĿ Àŧ Õ øÀǤǪǹɍǟ ʔÀƶ :**Histamine-like substances** ƙŋÀǪÊĿƵŸö ǦǒÀÎţǟ ǻǟzţǟ
ÿǟÀǳzŸĿÕ ŎȮö Ōŋ 1 ÿǟǼǺǪèÀǽ Û(167 ǦƜÀÔǟ Û1 ǼŸǑǟ) "Histamine-like substances ƙŋÀǪÊĿƵŸö ǦǒÀÎţǟ ǻǟzţǟ
.ÀǪǒ ƟŸĿţǟ Ž øÀǤǪǹɍǟ ǵǻŋ ȸŋ ŊŸŋ 25 ʔŸʒ ƁzǪƷ TS ƟƜŸŋ ȯzŸƬ ȸŋ ǈÊƨǟ ǦŸǪÕ ȸŋ

Sterility testing of ǦĮĿƩǟ ǧǟǻÀȒţǟ ǦŋÀǑʒ øÀǤǪǹǟ"øǽ ǦȍÀƪǟ ǵǻşÀzȷǟ Ɓǚ ÆĿǅǪÊÀ :**Sterility** ǦŋÀǑȞǟ
.ƟǝÀÎȢǟ ǴĿȉÀǪǟ øÀǤǪǹǟ ǦǑÀù ĘǤÛǪǽ Û(162 ǦƜÀÔǟ Û1 ǼŸǑǟ) "antibiotics

ÿǼǺǪÊÀ ."Gas chromatography ƁǟÀȢǟ ǟǟÀÎǪèɍǟ" ȷǟzÁʒ ǨƠ Ǧzzòzţǟ ǦÊÀǼţǟ ĘǤÛǩ :**Assay** ǦÊÀǼţǟ
ÿǼǺǪÊÀ .R ǼĿŋÀŋøzz ŎĿǰŋ ƟǝÀǪ ȸŋ ÀǪǒ ƟŸĿţǟ Ž R ȷzŧĿǪȷǟ ŎĿǼz ƟǪŸǪ ȸŋ ŊŸŋ 2 ƁzǪƷ ȯzŸƬ ƟŸǹǟǻ øÀĿȞŧ Õ
Ōŋ 10.0 ÛǦĿùzǦȒŋ ȷşǟzŋ ÛRS ƙÊĿŋzǼǪǑǤÊǟ ǼÀøzŸÕşøĿĿ ȸŋ ŊŸŋ 30 ǦǟÀę Ɓǚ ȢÀȒÀ (1) :ȷÀĿÕÀǪǟ ȷɍzŸŧ ǟ
ÀǅzøǦʒÀè ǵǼŋ ǷÀŀş ÛR hexamethyldisilazane ȷǟŸĿè ƟǝÀǪ ŎĿǰŋ ƟèǟǼè ȸŋ Ōŋ 1.0ş ƟŸǹǟǼǟ øÀĿȞţǟ ȸŋ
ƟǝÀǪ ŎĿǰŋ ƟèǟǼè ȸŋ Ōŋ 1.0ş ƟŸǹǟǼǟ øÀĿȞţǟ ȸŋ Ōŋ 10.0 øÀǤǪǹɍǟ ǵǻŋ ȸŋ ŊŸŋ 30 Ɓǚ ȢÀȒÀ (2)ş ÜȞÛŎǪŋ
1.3 ȼǒzù ƟǅÀǅzǟ ǻzŧʒş ƟøǦƬ ȸÀǩ ȢÀÎŌŋ ǦĿŸŧȞǟ ǦøĿ Ž ÿǼǺǪÊÀ .ȞÛŎǪŋ ÀǅzøǦʒÀè ǵǼŋ ǷÀŀş ÛR ȷǟŸĿè

[illegible] 5 [illegible] adsorbent [illegible] 0.4 [illegible] R4 [illegible] 95 [illegible] R [illegible] 265 [illegible] 270 [illegible] 215 [illegible] A [illegible] 90 [illegible] R [illegible] 1 [illegible] 2.5 [illegible] B [illegible] $C_{14}H_{24}N_2O_7$ [illegible].

[illegible]

Additional Requirements for Spectinomycin hydrochloride for parenteral use

[illegible] :**Bacterial endotoxins** [illegible] (30 [illegible] 5 [illegible]) "Test for Bacterial endotoxins [illegible] 0.09 RS [illegible].

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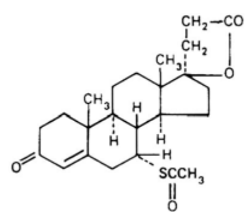
SPIRONOLACTONUM

Spironolactone [illegible]

$C_{24}H_{32}O_4S$:**Molecular formula** [illegible]

416.6 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

17-Hydroxy-7α-mercapto-3-oxo-17α-pregn-4-ene-21-carboxylic acid γ-lactone acetate; 7α-(acetylthio)-17-hydroxy-3-oxo-17α-pregn-4-ene-21-carboxylic acid γ-lactone; CAS Reg. No. 52-01-7.

[illegible] :**Description** [illegible].

ȳǿǯǯşǿǯŸỎӧӓ Ž ȷÅṡşǾӧӓ Àǵ ÜTS (ȯ/ȟ750~) ȯǯǷǯɋӓ Ž ā ӓşǽ ÜǒȦţӓ Ž ǺĔŸȶȝ ā ӓşǽ ɍ :**Solubility** ĞȄǷȦşǾӧӓ

.R

.ǿÆɳ :**Category** ĞȦÀӧӓ

.ǒǯȒӧӓ ȸɳ ĞȸȶȚ ÛǺÆĔǅ ĞŎŸȣɳ ĞȦşȦǵ Ž ȷǯǪȭɍǯǷşƘĞÊӧӓ ȘȦȜ ȷÜ Ƶ :**Storage** ȸȦÂǺǪӧӓ

ǥǿӓÀǵ ĞǅǿÆӓ ȦȦÆĔƮǪ ǻǿȦƮÔǷӓ ȷǯǪȭɍǯǷşƘĞÊӧӓ ɃÆĞȦ ȷÜ ȸȮǯ :**Additional information** ĞȄǯȦȑÜ ǧȦɳǯŸȞɳ

.ÆŸÔǪӧӓ ǥǻǯȞӓ ȜĞǪȽ ÛǺĞȦȭŎǩ ɏ 135

REQUIREMENTS ƘĞȗƱƘdž!ƒ

ȸȝ ÆȦÂȦ ɍş %97.0 ȸȝ ŌŌȦ ɍ Ȧɳ ɁŸȝ ȷǯǪȭɍǯǷşƘĞÊӧӓ Ƀǯǭȝ :**General requirement** ȳȦȞӧӓ ÆŸÛǪţӓ

.ĞȦÀŎӧӓ ǥǻȦţӓ ƂÜ ţǯǅȦӧȦӓ ĞӓǯÊȚ Û$C_{24}H_{32}O_4S$ ȸɳ %101.5

:**Identity tests** ȟȉǊǈǁ ǀƐƥƑƑƐ

• ȜȦƵ ȦɳÜ ǿȦĞǪǹɍӓ şÜ ȻǻȦȦɳ A ǿȦĞǪǹɍӓ ǧӓǿȦĞǪǹɍӓ B CŞ DŞ.

A: ƸǕÛȽ ǿȦĞǪǹɍӓ ȦȶȭǬ ǯȽ ȣǯǒǯɳ ƘƠ ȷӓǯȝ ǁȦĔǫ" âȦĔş" ƷȄÛӧӓ ɄǝǯȒӧӓ Ž ĞŎÛȦţӓ ƘƠ ǒӓȦȶƩӓ
ǒӓȦȶƩӓ ƘƠ ĞȞȉɉӓ ȋ ȦÔǪɳӓ ƷȄǜ ƸǯȦÛǪȦ .(43 ĞȞȦÔӧӓ Û1 ÆŸǑӧӓ) "Spectrophotometry in the infrared region
.ȷǯǪȭɍǯǷşƘĞÊŸӧ ɄȞǅȦţӓ ƷȄÛӧӓ ȝɳ şÜ RS ȷǯǪȭɍǯǷşƘĞÊӧӓ ȸȝ ǰǨȦӧӓ ƷȄÛӧӓ ȝɳ

B: ɃÆĞȦ ƷȄǜ ȋ ȦÔǪɳӓ ȯǯŸȚ 10 ȦĔȭȦǪӓ ȯǯǷǯǥǪǫȦɳ ȯǯɳ/ȳӓȦɖşȦǪɳ Ž ȯǯǷȦǯţӓ ÛR ÆȦȝ ȻǨÆȽȦȊɳ ȯǯǜӓ ǧȦǅǯɳ ƙӓ 230
ȯǯÛӓ ȴȅ 1 ĞǷȦǺȝӓ ĞŎĞǜ Ǝȝ ȋ ȦȶǪӧӓ ɳŸĞȦ ÛǺĞȦȭŎǩ ȦǪɳǯǷȦ 238 ĞǅǯţӓǬ ȯǯÛӓ ǺĔȶȚȝÜ ǺÆǵ ÛȦǪɳǯǷȦ 350ş ȦǪɳǯǷȦ
.ǺĞȦȭŎǩ 0.47 ӓǾȽ ĞǅǯţӓǬ

C: ǯȦ 10 ɳŸɳ 2 Ž ȸɳ ȒƥɳŌ ŌȦǿǯȦÊӧӓ (ȯ/ȟ700~) ÜTS ǰǪȦȦ ȯǯŸȚ ƃȦŎǨȦӓ şǽ ĘӧǨ ÆȦÆȉ ȦȒǹÜ
ȦȦÔɳ. ȸÅÊȦ ȯǯŸǂӓ ÜǷŸȦӓ ȯǯÆĞǪȦ ȷǯŸӧӓ ƂÜ ȦƥǰȰӓ ȸŌӓÆӧӓ ǿǯÛǨ ȝɳ ǿǯŸȅ ÆĔȦŸȅ ÛƘǅşǿÆĔȚӓ ƁǾӧӓ ȁǯÊȽ Ğǿ ǿşĞȅÜ ǧȦǪĔȅÜ
.Ȝ ȦȒǹ ȋ ȦǒȦӓ .R ǹÊÔȦ ȯǯŸǂӓ Ž ÜǒȦţӓ ǰǪȦȦ ȷǯŏÜ ÛȦȒƯ ȦȦǒÜ ȴȄȶȡ.

D: ĞǅǿǻÛ ɍӓ ÛǿȦƮÔǷɍӓ ĞӓȦȩ 204 ɏ ȝɳ ŌȮȦǪӧӓ.

ÜR ȳǿǯǯşǿǯŸỎӧӓ Ž ȯǯɳ/ɳŸɳ 10 ȦĔȭȦǪӓ ȯǯŸȚ ȳÆǺǪÊȦ :**Specific optical rotation** ɄȝǯÆӧӓ ɃȦÔĞӧӓ ȦȦşÆǪӧӓ

$.[a]_{\text{D}}^{20°\text{C}} = -33.0 \text{ to } -37.0°$

Chromium ȳşȦỎӧӓ: ȜȑǯȦ 0.20 ȟ ȝɳ 1 ȟ ȸɳ ȭǯȦǅǯǯ ǧȦǪǯ R ǯȄȅȦǯĞӧӓ ǧӓȦǪ ȸɳ 0.3ȟ ş R ǯȄȅȦǯĞӧӓ Ž ǯȦ ĞŎǩǯӓ
.ȷǯӓȦỎӧӓ ȯӓȦȦ ɁǿǪǵ ɏ 650-600 ǥǿӓÀǵ ĞǅǿÆӓ (ŌȞÎȦ) ÆɳȦȦş ÛǿȦƮÔǷɍӓ ɁǿǪǵ ƷÛȦӓ ȸǺÊȦ ÛȜȦǯ ÜĞȄÆĔƳӓ
ȸɳ ĞȄǯȦŏ ĞȄȶȮӓ ƷȦƩş ÛĞȉȦȦ ÛƷȄÛȦӧӓ ƙǺÊǪӧӓ ȳӓÆǺǪȅȦӓ ǒȦɳ ŌɳǪ 10 Ž ĞȦȮư ĞǅǿǻÛ ɁÔşÜ ƂÜ ĞǜȦȶȜӧӓ ā ӓǾǩ ÛǻƎȦ

[illegible] TS (v/v 190~) [illegible] R [illegible] 0.5 [illegible] 10 [illegible] 20 [illegible]
[illegible] TS. [illegible] 0.5 [illegible] 20 [illegible]
[illegible] 0.50 [illegible] TS (v/v 190~) [illegible] 1 [illegible]
[illegible] 0.5 [illegible] 20 [illegible] 100 [illegible] R [illegible] 2.83 [illegible]
TS. [illegible]

[illegible] **Sulfated ash** [illegible] 1.0 [illegible]

[illegible] **Loss on drying** [illegible] 105 [illegible] 5.0 [illegible]

[illegible] **Related substances** [illegible]
"Thin-layer chromatography (84 [illegible]) [illegible] R5 silica gel [illegible]
5 [illegible] R [illegible]
[illegible] 0.20 (B) [illegible] 20 (A) [illegible] R: [illegible]
[illegible]
[illegible] 15 [illegible]
[illegible] 105 [illegible] 10 [illegible] TS [illegible]
[illegible] A [illegible]
B. [illegible]

[illegible] **Mercapto compounds** [illegible] 2.0 [illegible] 20 [illegible] 10 [illegible]
[illegible] TS [illegible] VS (v/v 0.005) [illegible]
VS (v/v 0.005) [illegible] 0.1 [illegible]

[illegible] **Assay** [illegible] 10 [illegible] R [illegible] 100 [illegible]
[illegible] 1 [illegible] R [illegible] 100 [illegible] 10 [illegible]
[illegible] $C_{24}H_{32}O_4S$ [illegible] 238 [illegible]
47 ($A^{1\%}_{1cm}$ = 470).

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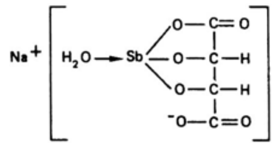
STIBII NATRII TARTRAS

Antimony sodium tartrate [illegible]

$C_4H_4NaO_7Sb$:**Molecular formula** [illegible]

308.8 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

Sodium aqua[tartrato(4⁻)-O^1,O^2,O^3]antimoniate(III); CAS Reg. No. 34521-09-0.

[illegible] scale [illegible] :**Description** [illegible]

.TS (~750 [illegible]) [illegible] 1.5 [illegible] :**Solubility** [illegible]

. [illegible] :**Category** [illegible]

. [illegible] :**Storage** [illegible]

[illegible] :**Additional information** [illegible]

. [illegible]

REQUIREMENTS [illegible]

[illegible] %98.0 [illegible] :**General requirement** [illegible]

. [illegible] $C_4H_4NaO_7Sb$ [illegible] %101.0 [illegible]

:**Identity tests** [illegible]

General [illegible] :A

[illegible] B [illegible] (123 [illegible] 1 [illegible]) "identification tests

. [illegible] 10

[illegible] 1.0 [illegible] TS (~70 [illegible]) [illegible] 1.0 [illegible] 0.05 [illegible] :B

[illegible] TS [illegible] - [illegible] TS [illegible]

.TS (ọ/ȟ80~) ӯζͶẩζÔӧӓ

General ǦդÅӉӧӓ ȢӓÀӉǪѐɼӓ ğӓøÅǤǪǹӓ" ɹӓζͶȝ ǨƠ Ȣζǜζʈӓ Ōȝ ÅÀǪӧӓ ɄÛӉͶ Üӧ Åդ Ōդ 0.2 Ž ŋŸդ 20 ā ӓØͶ :C .(123 ǦӇÅÔӧӓ Û1 ÆŸŎӓ) ğӓÀüÀÛŸӧ ÂƗʈʈõ "identification tests

stannated øÆÔǬʈӓ ŌͶøζŸõşøÆƗTӓ Ȓϸ ȡդ Ōդ 16 ȢÅȒͶş ŏÅդ Ōդ 10 Ž ӯӓÀȡ 1.3 ā ӓØͶ :**Arsenic** ǸƗφøÂӧӓ distillate ǥøÅÛǬӧӓ ắÅӉǩ ÛƵ ǯÒʈӓş ǦŸǱζΣӓ ŌÊȢǩ ÜŌդ 20 ÀǕŌͶş ÛƵ ǯÒդ ƂǕ ŌǜζͶ ÛǦŸǱζǵ Ž AsTS (ọ/ȟ250~) ǥøÅÛŌӧӓ ŌդÅӉǩ ÜŌդ 16 ǨÛŌǩ ắÅӉͶş AsTS ÀͶÆÔŌӧӓ ÆͶøζŸõ ọζŸƮ ȡդ Ōդ 0.05 ȢÅȒͶ ÛǦŸǱζΣӓ ƂǕ ğɼÅÊȢӧӓş ɼ Ǖ(130 ǦӇÅÔӧӓ Û1 ÆŸŎӓ) "Limit test for arsenic ǸƗφøÂӧӓ ŌǱǰ ɃÆΣӓ øÅǤǹɼӓ" ɹӓζͶȝ ǨƠ Ȣζǜζդ ζȽ Åʈõ .ӯӓÀȡ/ӯӓÀȡşÀÒդ 8 ȡդ ÀǯõǕ ǸƗφøÂӧӓ ʔζǪƮ ɹζÒͶ

ÅƗζÅǜ ŏÅդ Ōդ 10 Ž ȟ 0.50 ÂƗõÀǪӕ ọζŸƮ ɹζÒͶ :**Clarity and colour of solution** ọζŸǂӓ ɹζӧş ŏÅÀÔӧӓ .ɹζŸӧӓ ĆÆȝş

.ȟ/ŋŸդ 60 ȡդ ÀǯõǕ ÆŌÀӧӓ ɹζÒͶ ɼ Ǖ°ӯ 105 ǥøӓÀǵ ǦǱøÆӕ Ƶǡʑ :**Loss on drying** ƵƗÅǱǪŌÅӕ ÆŌÀӧӓ

ọζŸƮ ȡդ ğӓÀÛȩ ǥÆȝ ȢÅȒͶş ŏÅʈӓ ȡդ Ōդ 50 Ž ȟ 1.0 ā ӓØͶ :**Acidity or alkalinity** ǦͶζŸŌӧӓ şǕ Ǧȑζʈ Σӓ şǕ VS (ọ/ọζդ 0.01) ŌͶøζŸõşøÆƗTӓ Ȓϸ ȡդ ÅդǕ Ōդ 2 ȡդ ÀǯõǕ ÆŸÛǪͶ ɼ ǕTS ọζφÀǯͶqӓ/ọşÂͶÀõζդşƎӧӓ ǥÀȒǹ ƂǕ ǨÎǩ ɄøǪӧӓ (ÀȒǹǕ) ÀӉÎʈӓ ȡդ ǦÛѐζǪʈӓ ǦÛŌÀӧӓ ʔŸȝ ọζÔӇŸӧ VS (ọ/ọζդ 0.01) ӯζͶắζÔӧӓ ÆƗÊõşøÆƗȽ ȡդ .4.5 ŏÅȽÅӕ

ӯζͶắζǜ ğӓÀüÀü ȡդ ȟ 5 ȢÅȒͶ ÛŏÅդ Ōդ 50 Ž ÛǦƗüζǦȒդ Ǧφşàζդ Ûȟ 0.5 ǦӕӓÀȩ ā ӓØƚ :**Assay** ǦÊͶÅŌʈӓ ÀӉÎʈõ TS ÅÎͶӧӓ ӯӓÆǺǪѐÅӕ VS (ọ/ọζդ 0.05) ắζƗӧӓ ȝդ ÀͶÅӉͶ .R ӯζͶắζÔӧӓ ğӓøζӕ ɄȝÅӕø ȡդ ȟ 2ş R ӯζƗѐÅǩζӕ ȢÅȒͶ Ž ÀǹǕ ǥÀͶÅӉʈӓ. Ōõ 1 Ōդ ȡդ ắζƗӧӓ VS (ọ/ọζդ 0.05) üζÅÒͶ 15.44 ŋŸդ ȡդ $C_4H_4NaO_7Sb$.

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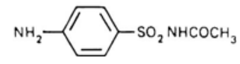
SULFACETAMIDUM

Sulfacetamide ǫĬǱǰƗĭ ƨƒǻǂƨ

$C_8H_{10}N_2O_3S$:**Molecular formula** ǦƗÅͶÂƨӓ ǦȢƗÔӧӓ

214.2 :**Relative molecular mass** ǦƗǦÊͶӧӓ ǦƗÅͶÂƨӓ ǦŸǪÒӧӓ

:**Graphic formula** ǦƗφÅƗǦʈӓ ǦȢƗÔӧӓ



Chemical name: [illegible]

N-Sulfanilylacetamide; *N*-[(4-aminophenyl)sulfonyl]acetamide; CAS Reg. No. 144-80-9.

Description: [illegible].

Solubility: [illegible] R [illegible] R [illegible] R [illegible] TS (~750 [illegible]).

Category: [illegible] Antiinfective.

Storage: [illegible].

REQUIREMENTS [illegible]

General requirement: [illegible] 99.0% [illegible] 101.0% [illegible] $C_8H_{10}N_2O_3S$ [illegible].

Identity tests: [illegible]

• [illegible] A [illegible] B [illegible] C.

A: [illegible] "Spectrophotometry in the infrared region" ([illegible] 1 [illegible] 43). [illegible] RS [illegible].

B: [illegible] "Related substances" [illegible] A [illegible] B [illegible].

C: [illegible] 0.10 [illegible] 5 [illegible] (~750 [illegible]) TS [illegible] 0.2 [illegible] (~1760 [illegible]) TS [illegible].

Melting range: [illegible] 181-184 [illegible].

Heavy metals: [illegible] 1.0 [illegible] 10 [illegible] 1.0 [illegible] (~300 [illegible]) TS [illegible] 40 [illegible] "Limit test for heavy metals" A ([illegible] 1 [illegible] 128) [illegible] 20 [illegible].

Solution in alkali: [illegible] 0.5 [illegible] 10 [illegible] (1 [illegible])

ɾş ÛTS2 ɃøȦȄȞţä ÿʐȶ8öä ȸɳ Ǵȓşǘ ǰǨȂȹ opalescence ÿʐȶȡ Ƀǘ ɿʐȮȂ ɾ şǘ ȞȄʐȦò ǰǨȂȂöä òʐŸǂä ɿʐȮȂ ÜVS ɿʐǒ" ɿäʐȂɜ ǨƠ 8ʐòʐɳ ʐȽ Ȧȶõ ȦȶȚǪȹøȦȱǑɳ ÆȂɜ Yw3 ɃøȦȄȞţä òʐŸǂä ɿʐǒ ȸɳ ÆȉǕ ǰǨȂȂöä òʐŸǂä ɿʐǒ ɿʐȮȂ .(53 ǴȞȦÔöä Û1 ÆŸǑä) "Color of liquids ǑəäʐÊöä

ǬȂøʐŸõşøÆȄȚä Ȑþ òʐŸȚ ȸɳ Ǒɳ 10 Ž ȟ 1.0 ÂȄõȀǪæ òʐŸȚ ɿʐȮȂ :**Solution in acid** ȐȶΣä Ž òʐŸǂä .TS2 ɃøȦȄȞţä ÿʐȶ8öä ȸɳ Ǵȓşǘ ǰǨȂȹ opalescence ÿʐȶȡ Ƀǘ ɿʐȮȂ ɾ şǘ ȞȄʐȦò VS (ȯ/òʐɳ 1)

.ȟ/ɳŸɳ 1.0 ȸɳ ȀǯõǗ ÈȄö :**Sulfated ash** ǨȂŸÊţä ǻȦɳȀöä

ȸɳ ȀǯõǗ ÆǬȦöä ɿʐȮȂ ɾ Ü°ÿ 105 ģøäȀģ ǴDZøÆæ ǨæȦǯöä ɿäʐǒ ʔøǪģ Ζȧʑ :**Loss on drying** ΖȄȦDzǪǒȦæ ÆǬȦöä .ȟ/ɳŸɳ 5.0

ǴǑȄęȀöä ǴǑǤÛöä āäȀÎǪèä" ɿäʐȂɜ ǨƠ 8ʐòʐɳ ʐȽ Ȧȶõ øȦǪȠɾä ĘǤÛȂ :**Related substances** ǴǑȦÎţä ǻäʐţä ǴŸȸ8ɳ ģǻȦȶõ R3 silica gel ȦǑȄŸȄÊöä ǴɳŸȽ ÿäÆǺǪèȦæ (84 ǴȞȦÔöä Û1 ÆŸǑä) "Thin-layer chromatography R ÆȄɳȦɳøʐʐ ǬȄǯȄɳ ɄəȦȀǪ òʐŸȚ ȸɳ Æģäş ȴDzģş R òʐǪȦǯȄţä ȸɳ ƙȶDzģş R ÿøʐʐşøʐŸǑöä ȸɳ ȞȶDzģ 20 ȸɳ ǰȂÂɳş òʐǪȦǯȂqä ȸɳ ÿʐDzģ 9 ȸɳ ǰȂÂɳ Ž ǴǪŸǪ ǬȄȶȦȚ ȸɳ ȀǪöşȀǑɳ 10 ǴȞȄȦÔöä ʔŸɜ ȞÔȂȂɳ ĘǤÛɫ .õȀȞǪɳ øʐÛõ ȀǪö ɄŸȄţä Ž øȦǪȠɾä ģǻȦɳ ȸɳ ɳŸɳ 2.5 (A) Ƀʐʒ :TS (ȯ/ȟ260~) ȦȄǪʐɳɟä ȸɳ Æģäş ȴDzģş TS (ȯ/ȟ750~) ɄŸȄţä Ž RS ÆȄɳȦǪȄèȦȂŸè òʐŸȚ ȸɳ ÿäȀȡşȀǑɳ 12.5 (C)ş ȀǪö ɄŸȄţä Ž RS ÆȄɳȦǪȄèȦȂŸè òʐŸȚ ȸɳ ɳŸɳ 2.5 (B)ş ǴʐȦƨä ǴȞȄȦÔöä ǽȀɫ .ğȦǤȂǾţä ȀǺǤǨ ʔøǪģ ǒäʐȚä Ž ΖDzǪö õȀǪǨ ÛāäȀ ÎǪèɾä ģȀDzģ ȸɳ ǴȞȄȦÔöä ţÂøȹ ÆȞæ .ȀǪö ģȀDzģ Ž àşȀǪȂöä ȸəȦǹÆö ȞøʐʐôȀȞǨş ÛǴǬȄęǻ 30 ģÆɳ °ÿ 105 ģøäȀģ ǴDZøÆæ ȸǺÊǨ ÛTS òʐǪȦǯȂǗ/ǬȂøʐȦŸÊöä ȐȶɯòʐŸȚ Ƀǘ ģȀÛę ȀǪǗ ģȀÛę TS (ȯ/ȟ700~) ǬȂøʐȦŸÊöä Ȑþ ǴʐȦȓǖæ àşȀǪȂöä ȸəȦǹǻ ǯȦǪǗ ȸȮΣ) ǴǬȄęǻ 15 ģÆɳ ǴǬŸ8ɳ øȦȄǨ Ž ǴȞȄȦÔöä ɜȓʐǩ .(Ǒɳ 100 Ž R ÿʐȄèȦǨʐǤöä ÆȂǻʐȂ ȸɳ ȟ 3ş R ÿʐȂǻʐÔöä ǨȂȀǪ òʐŸȚ ȸɳ ȟ 10 Ƀʐǫʒ *N*-(1- naphthyl) ƙɳɟä ɄəȦȀǪ ƙŸȄǯȂǗ (ǬȄǯʐȦǪ-1)-*N* ÆȂøʐŸõşøÆȄȽ òʐŸȞɳ æȀȞş ǴǬȄęǻ 15 ģÆɳ ȕʐäǻ ǒäʐȽ ȔÛƯ ȎȞȂȂş ǣäǣøqä ģǻȦɜǗ ǑǤę ΖDzǪö õȀǪǨ ÛģøşȀȒöä ÆȂɜ .TS òʐǪȦǯȂǗ/ethylenediamine hydrochloride ȸɳ ģÆǕ ȀǯõǗ ÛǴȄÊȄəȀöä ǴǨǑǤöä ǒȦǯǪèȦæ ÛA òʐŸǂȦæ ȦȚȄŸɜ ǑÔȞǪÊȂ ǴǨǑæ ǴȂǗ ɿʐȮǨ ɾ .øȦȚȂöä ǒʐȓ Ž āäȀÎǪèɾä .C òʐŸǂȦæ ȦȚȄŸɜ ǑÔȞǪÊȂ ɄøǪöä ǴǨǑǤöä

Û1 ÆŸǑä) "Nitrite titration ǨȂȀǪȂöä ģȀȂȦȞɳ" ɿäʐȂɜ ǨƠ 8ʐòʐɳ ʐȽ Ȧȶõ ǴÊȂȦǑţä ʔȀθ :**Assay** ǴÊȂȦǑţä ǬȂøʐŸõşøÆȄȚä Ȑþ ȸɳ Ǒɳ 20 ȸɳ ǰȂÂɳ Ž ǴææǾɳ ÛǴȄȕʐǤȒɳ ǴǪşàʐɳ Ûȟ 0.5 ǴææȀę ÿäÆǺǪèȦæ .(143 ǴȞȦÔöä 0.1) ÿʐȂǻʐÔöä ǨȂȀǪ ȸɳ Ǒɳ 1 Ǒõ .VS (ȯ/òʐɳ 0.1) ÿʐȂǻʐÔöä ǨȂȀǪæ ȀȂȦȞş ÛǑȦɳ Ǒɳ 50ş TS (ȯ/ȟ250~) .$C_8H_{10}N_2O_3S$ ȸɳ ɳŸɳ 21.42 ȕʐȦǑȂ VS (ȯ/òʐɳ

øøøøø

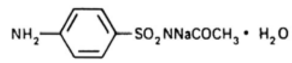
SULFACETAMIDUM NATRICUM

Sulfacetamide sodium [illegible]

$C_8H_9N_2NaO_3S,H_2O$:**Molecular formula** [illegible]

254.2 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

N-Sulfanilylacetamide monosodium salt monohydrate; *N*-[(4-aminophenyl)sulfonyl]acetamide monosodium salt monohydrate; CAS Reg. No. 6209-17-2 (monohydrate).

.Sulfacylum-natrium [illegible] :**Other name** [illegible]

[illegible] :**Description** [illegible]

[illegible] TS (~750) [illegible] 1.5 [illegible] :**Solubility** [illegible]
R [illegible] R [illegible]

.Antiinfective [illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

[illegible] :**Additional information** [illegible]

REQUIREMENTS [illegible]

[illegible] %99.0 [illegible] :**General requirement** [illegible]
$C_8H_9N_2NaO_3S$ [illegible] %101.0

:**Identity tests** [illegible]

• [illegible] A [illegible] B [illegible] C [illegible] D.

A: [illegible] 1 [illegible] 10 [illegible] 2 [illegible] TS (300) [illegible]
[illegible] 105 °[illegible] [illegible]

Spectrophotometry in the infrared [illegible] (43 [illegible] 1 [illegible]) "region [illegible] RS [illegible].

B: [illegible] 183 [illegible] A [illegible].

C: [illegible] 0.1 [illegible] 5 [illegible] A [illegible] (~750[illegible]) TS [illegible] 0.2 [illegible] (~1760[illegible]) TS [illegible].

D: [illegible] General [illegible] identification tests" (1 [illegible] 115) [illegible] B [illegible] 0.5 [illegible] (~60[illegible]) TS.

Clarity and colour of solution: [illegible] 0.5 [illegible] 10 [illegible] R [illegible] Yw1 [illegible] "Colour of liquids [illegible] (1 [illegible] 53).

Water: [illegible] Determination of water by the Karl Fisher Method" (1 [illegible] 145) [illegible] 0.2 [illegible] 60 [illegible] 80 [illegible].

pH Value: [illegible] 0.05 [illegible] R [illegible] 8.0-9.5.

Related substances: [illegible] "Thin-layer chromatography (1 [illegible] 84) [illegible] silica gel R6 [illegible] 50 [illegible] 1-[illegible] R [illegible] 25 [illegible] (~260[illegible]) TS [illegible] R [illegible] 25 [illegible] 10 [illegible] 0.10 (A) [illegible] 0.50 (B) [illegible] 5 [illegible] RS [illegible] 0.25 (C) [illegible] RS [illegible] 4-[illegible] TS5 [illegible] B [illegible] C.

Assay: [illegible] "Nitrite titration (1 [illegible] 143) [illegible] 0.5 [illegible] 50 [illegible] 20 [illegible]

ӯzʌǻzÔöä ǨʌÀʘ ȸŋ Àʘö ɄŸĒŋ 1 Ȫõ .VS (ȯ/ȯzŋ 0.1) ӯzʌǻzÔöä ǨʌÀʘǣ ÀʌȞʌş ÛTS (ȯ/ȟ70~) ȬʌøzŸõşøǼŢä
.$C_8H_9N_2NaO_3S$ ȸŋ ŊŸŋ23.62 ǜzȦÒʌ VS (ȯ/ȯzŋ 0.1)

ØØØØØ

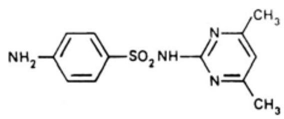
SULFADIMIDINUM

Sulfadimidine ǄĭǫĭǄĭǫƑƻƨǁƐ

$C_{12}H_{14}N_4O_2S$:**Molecular formula** ǴǼȦʌÂƨä Ǵ8ǼÔöä

278.3 :**Relative molecular mass** ǴǼǴÊʌöä ǴǼȦʌÂƨä ǴŸʘÒöä

:**Graphic formula** ǴǼȹȦǼǴţä Ǵ8ǼÔöä



:**Chemical name** ɄəȦǼŧǼÒöä ǈèɼä

N^1-(4,6-Dimethyl-2-pyrimidinyl)sulfanilamide; 4-amino-*N*-(4,6-dimethyl-2-pyrimidinyl)benzenesulfonamide; CAS Reg. No. 57-68-1.

.sulfamethazine ȸʌàȦǯǼŋȦÀŸè ÛSulfadimezinum ӯzʌʌÂǼzǻȦÀŸè :**Other names** ʔÀǹÛ öȦƧÛ

.ǼǴʌÀȬǩ ǴHəäÀöä ȻǼʒ şÛ ǴHəäÀöä ȻǼʒ ÜɄzÀõ ȒǼǣÛ şÛ ɉzŸöä ȒǼǣÛ ÛɃøzŸǣ ȧzHÊŋ :**Description** Ȥòzöä

Ž āȧşǽ ÜTS (ȯ/ȟ750~) ȯzȹȦǯʌɋä Ž ɉȦǣşØöä ǴǼHʅ ÜöȦţä Ž ǼǼǄ ɉȦǣşØöä ǴǼHʅ :**Solubility** ǴǼȹȦǣşØöä
.R ȻʘɉȦä Ž ǼǼŸŧʒ āȧşǽ ɼ ÜR ɉzʘǼèɉȦä

.ǈǼʘäÀƨä ǻȦȒŋ öȧşǻ :**Category** ǴȦÀöä

.özȒöä ȸŋ ʔŧHł ɉÛş ÛǼǼǼǄ ǴȪŸ8ŋ Ǵʌşȧǵ Ž ȸʌǼǼzǻȦÀŸÊöä ȘȦʒ ɉÛ Ǽz :**Storage** ȸʌÂǺʘöä

REQUIREMENTS ƘǴǆǖƱƙǆǃ!ƒ

%100.5 ȸʒ ǼʌÂʌ ɼş %99.0 ȸʒ ȪȪʌ ɼ Ȧŋ ʔŸʒ ȸʌǼǼzǻȦÀŸÊöä ɃzʘƷ :**General requirement** ӯȦȞöä ǼŸÛʘţä
.ǴȦÀÒä ǵǻȦţä ƂÛ ţzǄÀöȦǣ ǴǣzÊȚ Û$C_{12}H_{14}N_4O_2S$ ȸŋ

:**Identity tests** ǶĭǊǋǁƐ ƖƐƥƑǴƗƐ

- ȸÒz ǴǼǴÛǩ ɼäȹȦʘÒɼä A ȻǻÀÀŋ şÛ ǧȧøȦʘÒɼä B Ʒş CƷ Ʒş D.

Spectrophotometry in ŏăÀŧΣă ŇƠ ĞỖÛÀţă Ž ƟəζȒöă ȤĔÛöă ȃÀĔę" ȷăζÀ3 ŇƠ 8ζờζţă øÀǪṅɍă ĘĜÛł :A

ȸŋ ǰķÀÀöă ȤĔÛöă 3ŋ ŏăÀŧΣă ŇƠ ĞĦìȷă îÀÔǪŋă ȤĔù ĘæÀÛǪÀ .(43 ĞĦÀÔöă Û1 ÆŸŎă) "the infrared region

.ȸÀÆĔɕắÀÀŸÊŸö ƟĤDZÀţă ȤĔÛöă 3ŋ şǕ RS ȸÀÆĔɕắÀÀŸÊöă ȯζŸȚ

ğăøÀǪṅă" ȷăζÀ3 ŇƠ ĞĔöşȷă ĞĔķÀŋşøȷă ğÀÆĔŋȷă 8ăÀĤǪèɍ 8ζờζţă Ō3ÀÀǪöă ĦĜÀÕŏk ȟ 0.05 ƟÛĤÀ :B

.ĞĔöÀÕķÀæ ĞæÀèø ĦDZǪÀŋ Û(119 ĞĦÀÔöă Û1 ÆŸŎă) "General identification tests ĞŋÀĤöă 8ăÀĤǪèɍă

.(ƙǪÕĔęắ ĞæăÀę) ĞæÀèø ŌÒÎǪķ ɁøǪǵ TS (ȯ/ȟ700~) ŌÀøζÀŸÊöă ȒƥȸŋŌŋ 1 3ŋ ȟ 0.5 ȤÛŸæ ɁŸ8À :C

.R ƘǪȷă ȸŋ Ōŋ 20 øæ ǰÀÀţă ỜŸẮǪÊÀş TS (ȯ/ȟ80~) ӯζÀắζÔöă ÆĔÊỖşøÆĔŁ ȯζŸȚ ȸŋ Ōŋ 15 8ÀȒÀ ÛắĦÀ

ĞDZøắ .ƟəÀŋ ӯÀƥ ɁŸ3 8ÀÀƨă ɁøǪǵ ÀẮĜÀş R ĞĔəÀŋŸöă ӯζÀắζÔöă ğÀÀŸè ȸŋ ĞỖĜù Ǝ3 ƘǪȷă ĞờŸṅ ǴìÀķ

.(ȸÀÆĔɕƘæ ŌĔǯĔŋ ƟəÀÀǪ-6.4-ζÆĔŋǕ-2) °ӯ 153 ĞæăÀę ÛøÀȚÔǪɍă

.ỖÒÀǪöă 3ŋ ĦĜÀÕŏk °ӯ 197 ÛøÀȚÔǪɍ ĞDZøắ :D

øÀǪṅɍă" ȷăζÀ3 ŇƠ 8ζờζŋ ζŁ Àŧỗ ȟ 1.0 ŌŧĤǪÊÀ øÀǪṅɍă ȯζŸȚ ƘȒĦǪö :**Heavy metals** ĞŸĔỖǯöă ȷắÀĤţă

Ɂζǂ‡ă ȸĦĤÀ Ü(127 ĞĦÀÔöă Û1 ÆŸŎă) 4 ŏăÀDZȷă ÆÊШ "Limit test for heavy metals ĞŸĔỖǯöă ȷắÀĤţă ŌDZȷ ɃÆΣă

.ȟ/ӯăÀȡşÀÒŋ 20 ȸŋ ÀǯỗǕ ȷζÒÀ ɍ Ü(128 ĞĦÀÔöă Û1 ÆŸŎă) A ĞỖÀÀÛŸö ĦÖζş ĞŸĔỖǯöă ȷắÀĤţă ȸŋ

.ȟ/ŋŸŋ 1.0 ȸŋ ÀǯỗǕ ÈĔö :**Sulfated ash** ŇÀŸÊţă ắÀŋÀöă

ȸŋ ÀǯỗǕ ÆỖÀöă ȷζÒÀ ɍ Ü°ӯ 105 ǥøăÀǵ ĞDZøÆæ ŇæÀǯöă ȷàζöă ɁøǪǵ ȤÀƶ :**Loss on drying** ȤĔÀDZǪöÀæ ÆỖÀöă

.ȟ/ŋŸŋ 5.0

°ӯ 70 ǥøăÀǵ ĞDZøÆæ R ȷζæÀÒöă ÆĔÊỗǕ ƟəÀÀǪ ȸŋ ƃÀǃă ŏÀţă ȸŋ Ōŋ 100 3ŋ ȟ 2 ȸẮÊÀ :**Acidity** Ğȑζŧ Σă

ӯăÆẮǪèÀæ ÛVS (ȯ/ȯζŋ 0.1) ӯζÀắζÔöă ÆĔÊỖşøÆĔŁ ȯζŸĦŋ ĞæÀèÀöă ȸŋ 25 ÀÀĤÀ .ǴŋìÀÀş ắĦÀ ÛĘəÀęắ 5 ǥÆŋ ĦĜÀÕŏk

ÀĤÎţă ȸŋ ĞÛèζǪţă ĞÛỖÀöă ɁŸ3 ȯζÔĦŸö Ōŋ 0.2 ȸŋ ÀǯỗǕ ÆŸÛǪÀ ɍ ÜÀĤÎŧỗ TS ȯζǵÀǯÀǕ/ȯζŧĔζŋşÀæ Ğęøà

.(ÀȒṅǕ)

ĞỖĔęÀöă ĞỖĜÛöă ȃăÀÎǪèă" ȷăζÀ3 ŇƠ 8ζờζŋ ζŁ Àŧỗ øÀǪṅɍă ĘĜÛÀ :**Related substances** ĞŏÀÎţă ắăζţă

15 ȸŋ ǰÀÂŋş ĞŸǂ8ŋ ǥắÀŧỗ R3 ÀÒĔŸĔÊöă ĞŋŸŁ ӯăÆẮǪèÀæ (84 ĞĦÀÔöă Û1 ÆŸŎă) "Thin-layer chromatography

10 ĞĦĔÀÔöă ɁŸ3 ŸÔÀÀŋ ĘĜÛł .ŏÀĦǪŋ øζÛỗ TS (ȯ/ȟ17~) ÀĔǵζŋȷă ȸŋ ӯζDZǵ 3 ÛR ȯζǵÀķζæ-1 ȸŋ ĦŧDZǵ

ȯζŸȚ ȸŋ ŋŸŋ 0.050 (B)ş ÀǪö ƟŸĔţă Ž øÀǪṅɍă ǥắÀŋ ȸŋ ŋŸŋ 10 (A) Ƀζ3 :R ȷζǪèȷă Ž ƙȯζŸȚ ȸŋ ÀǪöşÀÒŋ

10 ǥÆŋ ӯ 105 ǥøăÀǵ ĞDZøÆæ ȸẮÊķ Ûȃ ăÀÎǪèɍă ǥÀDZǵ ȸŋ ĞĦĔÀÔöă ţÂøǪ ÆĤæ .ÀǪö ƟŸĔţă Ž RS ÆĔŋŸĔǪÀÀŸÊöă

ŏÀÀǯǪèÀæ ÛA ȯζŸ‡Àæ ÀȚĔŸ3 ŌÔĦǪÊÀ ĞĤỖæ ĞÀǕ ȷζÒķ ɍ .TS3 ÆĔŁÆöăÂøÀæ ζÆĔŋǕ ŌĔǯĔŋ ƟəÀÀǪ-4 ȯζŸĦŋ æÀķş ĘəÀęắ

.B ȯζŸ‡Àæ ÀȚĔŸ3 ŌÔĦǪÊÀ ƟøǪöă ĞĤỖĜöă ȸŋ ǥÆì ÀǯỗǕ ÛĜĔÊĔəÀöă ĞĤỖĜöă

Û1 ÆŸṎä) "Nitrite titration ǨÀQÄöä gÀÅǨŋ" ȷäɀÅǨöä ǨƠ ȣɀòɀŋ ɀȴ Åŋ ÆÊɯ ĞÊÅṎţä ʔÀθ :**Assay** ĞÊÅṎţä
ÛTS (ȯ/ȟ70~) ÕÀøɀŸÕşøÆȽä Ȑȡ ȸŋ Õŋ50 Ž ā äØǩ ÛĞȄüɀĞȒŋ Ğɸşàɀŋ ÛÃĞÀÕǩ 0.5 ÿäÆǺèÅæ Û(143 ĞȞÀÔöä
ŋŸŋ 27.83 ùɀÅÒÀ VS (ȯ/ȯɀŋ 0.1) ÿɀÅǻɀÔöä ǨÀQɸ ȸŋ ÀQö ɄŸȄŋ Õõ .VS (ȯ/ȯɀŋ 0.1) ÿɀÅǻɀÔöä ǨÀQÄæ ÀÅǨÀş
.$C_{12}H_{14}N_4O_2S$ ȸŋ

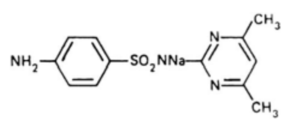
SULFADIMIDINUM NATRICUM

Sulfadimidine sodium !ǋǰǫǋTǁǫ ǅǰǫǐǅǰǫƑƻǂƨ

$C_{12}H_{13}N_4NaO_2S$:**Molecular formula** ĞȄÅÂƨä Ğ8ȄÔöä

300.3 :**Relative molecular mass** ĞȄĞÊÅöä ĞȄÅÂƨä ĞŸQÒöä

:**Graphic formula** ĞȄɸÅȄĞţä Ğ8ȄÔöä



:**Chemical name** ɄəÅȄȶȄÒöä ȴèɼä

N^1-(4,6-Dimethyl-2-pyrimidinyl)sulfanilamide monosodium salt; 4-amino-N-(4,6-dimethyl-2-pyrimidinyl)benzenesulfonamide monosodium salt; CAS Reg. No. 1981-58-4.

.ÅĞÀÕǩ ĞȞəäÀöä ĆÆȝ şÛ ĞȞəäÀöä ĆÆȝ ÜɄɀÀõ ȐȄæÛ şÛ ȷɀŸöä ȐȄæÛ ÛɃøɀŸæ ȧɀȞÊŋ :**Description** Ȥòɀöä

.TS (ȯ/ȟ750~) ȯɀɸÅǯQä ȸŋ ÅõÂǅ 60ş õÅţä ȸŋ õÂǅ 2.5 Ž ā äşæ :**Solubility** ĞȄɸÅæşØöä

.ȴȄɸäÀƨä åÅȒŋ õäşå :**Category** ĞÅÀöä

.õɀȒöä ȸŋ ʔȶȝ ȷÛş ÛȄÆȄǅ ĞÕŸ8ŋ ĞÀşÅǵ Ž ÿɀÅǻɀÔöä ȸÀÆȄɀåÅÀŸè ŞÅȝ ȷÛ Æʑ :**Storage** ȸÂÂǺQöä

ÛÆüÀöä ɀǅŸõ ȼȑÀǨǩ ÆÀȝ ǰÀøÆQöÅæ ÿɀÅǻɀÔöä ȸÀÆȄɀåÅÀŸè õøÆQÀ :**Additional information** ĞȄɀÅȑÛ ğÅŋɀŸǨŋ
.ĞǨÅǨÀţä gøäÀΣä ğÂǅøå Ž ţÀèÛ ÕÒÅQöä ǴĞÔÀş ÛõɀȒöä āÅȄ8æ ʔøQǵ

REQUIREMENTS ƘĞǜǁƱǩǳ!ƒ

ȸȝ ÆÀÂÀ ɼş %98.0 ȸȝ ÕÕÀ ɼ Åŋ ʔŸȝ ÿɀÅǻɀÔöä ȸÀÆȄɀåÅÀŸè ɃɀQȝ :**General requirement** ÿÅǨöä ÆŸÛQţä
.ĞÀÅÕä gåÅţä ƁÛ ţɀǅÀöÅæ ĞæɀÊƮ Û$C_{12}H_{13}N_4NaO_2S$ ȸŋ %101.0

:**Identity tests** ƕǰǋǈǁǫ ǀ ǫƥƑǴǇǫ

• ȸȮǤ ȸǾȺǛǻǨǼȲǵȆǚǿȢ A ǷǤ ǶȶǬǨǼȲǵȆǚǿȢ B ǷǤ Cǻ .Dǻ

A: ȠǢǞȇ 0.1 ȟ Ǝ 10 ǺȱǿǴ ǺǤ Ǜǻȧǥȶ ȐǾǛȮǥǘ ȜǿǾǍǣǫǾǀǾȸǚ ǪǾǾȳǵȤǾǺǾǍǤ ǮǾǬȸǾȶǾǽǿǺǜǮ (~70ǜǴǽ/ǀ) TS ȸǾȺǛǻǨǼȲǵȆǚǿȢ ǞǽǺǽǩǽǻǭǧ ȗǎǠǤ ǨǼǩǾǧǽǾǿǶ ǮǾǬȸǾȶǾǽǿǺǜǮ ȾǩǤ ǻǚǿǾǬȶǾǽǿǺǽǮ ǼǶ ǠǺǿǶ ȸǽǾǻǵǿ ǣǤǦǪ ǾǡǾǞǽǬǺǥǤǾ Ǝ ǨǽǡǤȸǾǺǟǞǽǺǽǩǽǻǭ 105 ǰǺǽǬǤǟ .

ǸǾǬǮǨǛ ǞǾǺǿǶ ǴǿǹȧǹǴǼǡǥ ǾǡǾǜǽǬǚǺ ǬǽǭǯǽǢ (ǩǼȚǿǭǜǶ 43 ǿǜǾǯ) .ǞǽǻǺǵǥǿ ǬǠǽǴǻǞǧǽǰ ǝǾǺ ǸǽǡǥǾǴǻǥǞ ǴǠǥǾǸǵǡǽǤǿǶǾǜǞǿǪǾǡǶǾǽǵǛǾ "Spectrophotometry in the infrared region

B: ȠǢǞȇ 0.1 ȟ Ǝ 10 ǺȱǿǴ ǺǤ 2 ȱǾǛǚ ǺǤ ǟǽ ǵǠǼ (~300ǜǴǽ/ǀ) TS ǶǾȶǵǦǼǾǞ ǝǾǭǾǞǽǟǭǚȗǥǺ ǬǾǭǾǺǩǾǠǦ ǩǾǡǽǬǭǿǭ
ȶǾǽȯǿǼǿǾǝǟǽǷǿ ǞǺȡǞǞǾǸǾǿǦǰǤǷǿǿǦǽǞȡǾǿǢ ǮǽǾǣǾȗǿ ǦǾǵǽǛǮǠǿǾǯǬ ǚǤǚ ǻǽǤǽǾǩǠǧǥǧǼǠ .ǩǽǺǽǞǾǿǺǿǬǥ ǾǡǾǢ ǦǤǷǺǝǥ
.ǚǽǻǾǠǥǾ ǩǾǢǤǺǝǮǻǬǹ ǮǽǾǥ ǟǦǶǽǦ (119 ǿǜǾǯǭǢǟ 1ǡ ǻǜǾǤǽ) "General identification tests ǿǺǤǧǡǺǿǿǻ ǩǿǽǦǮǺǡ

C: ǢǽǞ 0.5 ȟ ǟǪ 1.5 ǺȱǿǴ ǺǤ ǟǽ ǵǠǼ ǜǾǬǪǽǾǺǽǾ (~700ǜǴǽ/ǀ) TS ǹǺǥǬ ǩǾǩǞǽǩǤǷǿ ǞǾǬǾǽǿǺǤ ǥǿǥ
ǺǤ ǺǤ 20 ǾǦǾǤǞǽ ǺǿǤǥǾǹǿǩ TS (~80ǜǴǽ/ǀ) ǽǺǽǦǾǜǽǮ ǻǜǶǭǣǽǪǾǩǥǸǡǞ ǺǤ ǺǤ 15 ǩǾǾǿǛ ǮǾǡǾǭǥ .(ǹǾǿǾǽǺǞǥ
.ǣǾǺǞǽ ǺǽǶ ǡ ȱǾǿǴǮǿ ǯǦǽ ǚǽǿǧǻǦ R ǿǾǺǛǺ ǽǽǿǽǾǫǺǿǽǫ ǢǠǪǽǩǤǾ ǺǤ ǿǤǥǤ Ǜǫ ǿǽǤǞǾǾ ǿǤǽǾǤǿǤǥǿǞǾ .R ǹǾǿǺǿǿ
.(ǷǻǡǥȇǤǾǨǽǵǚǽ ǾǩǣǺǽǷǡǽǽǦǬǽ-6.4-ǶǾǞǤ-2) ǜ 153 ǿǧǾǞǽ ǮǾǦǿǤǦǿǞǽǟ ǿǞǭǥǽǾǾ

D: ǥǽ ǩǞǼǽǺ ǼǽǺǥǾǨ ǬǽǩǿǥǥǾǺ ǾǿǻǾ ǾǽǵǾǺ ǩǿǺǽǨǽǻǬǵǿǢǿ ǞǾǡǿǦǾǠǡǽǣǾǜ ǩǾǽǦǮǺǡ ǿǺǤǧǡǺǿǿǻ General
identification tests" (123 ǿǜǾǯǭǢǟ 1ǡ ǻǜǾǤǽ) ǦǾǫǾǽ ǝǽǦǿǧǥǿǝ .ǝǽǞǿ ǿǽǾ ǽǽǦǟǞǽǦ ǾǽǵǾǺ ǩǥ B ǣǠǨǤ (ǿǞǛǥ) ǺǽǶǢǥǤ
.(~60ǜǴǽ/ǀ) TS ǶǾȶǵǦǼǾǞ ǝǾǭǾǞǽ Ǝ ǿǾǞǥǾǜǽ ȠǢǞȇ ǥǪǢǺǝ

Heavy metals ǽǞǾǿǿǽǥ ǟǽǤǥǧǿǞ: ǩǟǭǿǷǽ ǿǦǽǦ ǾǽǵǾǺ ǩǥǞǞǿǮǿǼ 1.0 ȟ ǾǿǥǠ ǟǽǡ ǞǻǥǼǥǥǺ ǾǻǵǦǵǾ ǿǿǼǽǽǩ ǩǾǽǦǮǺǡ ǾǽǵǾǺ ǩǿǦ
ǾǽǥǿǵǤǿǝ "Limit test for heavy metals ǿǞǾǿǿǽǥ ǟǽǤǥǧǿǞ ǾǽǦǾǦǼǽ ǬǵǦ 4 (127 ǿǜǾǯǭǢǟ 1ǡ ǻǜǾǤǽ) ǩǭǽ ǾǦǽǽǝǣ ǬǽǤǾǽ
.ǀ/ǺǤǦǟǽǾǬ 20 ǺǤ ǦǾǦǽ ǩǺǽǩ ǥ ǟ(128 ǿǜǾǯǭǢǟ 1ǡ ǻǜǾǤǽ) A ǿǽǥǦǾǤǽǾǦǷǥ ǿǞǾǿǿǽǥ ǟǽǤǥǧǿǞ ǺǤ

Clarity and colour of solution ǩǿǽǦǾǽ ǩǤǿ: ǽǾǦǣǥǼǽ 3.3 ȟ Ǝ 10 ǺȱǿǴ ǺǤ ǿǾǥǵǽ ǾǽǬǞǽ
ǺǽǷ ǢǾǵǾǥ ǾǽǮǥǦǺ ǪǾǞǽ Yw4 ǼǺǬǝǿǽ ǩǽǿǽ ǿǩǽ ǺǤ ǾǡǞǽ ǿǿǺǤǥ ǩǿǽǦǾǽ ǥǩ ǟǩǬǩǦǤ ǺǦǽǺǿǽǥ ǾǾǤǿǣǾǦ ǝǽǞǿ ǺǤ
.(53 ǿǜǾǯǭǢǟ 1ǡ ǻǜǾǤǽ) "Colour of liquids ǿǿǶǾǥǤǾ ǩǾǦ" ǽǞǽǦǽ ǩǦǤǺǤ ǩǦǤǺǤ

Loss on drying ǿǽǦǽǦǤ ǾǦǾǽǩǤ: ǿǽǭ ǽǽǥ ǾǿǢǤ ǞǬǽǬǥǿ 105 ǩǾǽǥ ǥ ǩǺǿǩ ǾǦǦǥǾǦǽ ǦǾǦǽ ǺǤ
.ǀ/ǺǤǦ 20

pH Value ǾǦǾǽǥǤǽ ǽǻǦǤ: ǥǽǦǤǾǽǩ 0.10 ȟ/ǺǤ Ǝ ǺǤǞ ǩǽǽ ǺǤ ǾǽǦǼǽ ǩǦǤǺǤǥǽ ǩǤǾǥǽ R0.10-0.11.

Related substances ǩǿǽǥǦǿǞ ǥǽǽǡǥǿǦ: ǩǾǽǦǮǺǡ ǾǽǵǾǺ ǩǿǦǞǞǿǮǿǼ ǩǦǤǺǤ ǽǞǽǦǽ "ǟǿǦǾǥǽ ǽǥǿǦǾǥǤǽǥǽǞǿǝǿ
"Thin-layer chromatography (84 ǿǜǾǯǭǢǟ 1ǡ ǻǜǾǤǽ) ǽǤǾǦǥǤǞ ǦǾǭǾǥǤǥǽ R3 ǥǞǿǦǽǥǿ ǿǽǮǾǥǽǦǤǦǺ 15 ǺǤ
ǺǤǟǾǿǦǾǤǾǮ ǺǤ 1-ǩǺǾǽǞǾǥǦ R ǩ3 ǿǽǺǤǦǤǾǦ ǺǤ ǦǥǽǺǤǤǽǥǟ (~17ǜǴǽ/ǀ) TS ǿǽǦǽǵǦǞ .ǿǽǦǽǮǤ ǾǩǦǤ ǥǽǩǦǤǥǽǞ 10

(ὀ/ȟ260~) ǺĔφζηɟǟ ȸη Ǽǵǟş ȴǅǵş TS (ὀ/ȟ750~) ὀζφǺǯΛqǟ ȸη ȳζǅǵ 9 ȸη ǰΛÂη Ž ƙὀζŸƮ ȸη ǺQὅşǺὈη ǺQὅ ɄŸĔƫǟ Ž RS ǼĔηŸĔφǺǺŸÊὅǟ ὀζŸƮ ȸη ŊŸη 0.050 (B)ş ǺQὅ ɄŸĔƫǟ Ž ǿǺǤQǹɼǟ ǥǻǺη ȸη ŊŸη 10 (A) Ƀζʒ :TS ȸη ȳζǅǵ 9 ȣǺȒΛ ǗTS (ὀ/ȟ260~) ǺĔφζηɟǟ ȸη ǦŸĔŸę ǦĔȶȭ Ž ǿǺǤQǹɼǟ ǥǻǺη ŀɼşǗ ǟǟǾǩ ǗA ὀζŸǂǟ ƘȒȞQὅ) ȸη ǦȞĔǺȎὅǟ ƫÂøφ ǼĤǣ .(ǺĔφζηɟǟ/ὀζφǺǯΛqǟ ǰΛÂη ȳǟŸὅǟ ȴǅΣǟ ƂǗ ǾǝǼΛʒ ƵǺƷş ǗTS (ὀ/ȟ750~) ὀζφǺǯΛqǟ

.TS3 ǼĔȽǼὅǟÂøǺǣ ζǼηǗ ȬĔǯη ɄǝǺǺǬ-4 ὀζŸȞη ǣǺƙş ƐǝǺęǻ 10 ǥǼη °ȳ 105 ǥǿǟǺǵ ǦǅζǿǼǣ ȸǺÊǩ Ǘ ǟǟǺÎQɘɼǟ ǥǺǅǵ ǺǮĔŸʒ ȬȎȞQÊΛ ɄøQὅǟ ǦȞǬǦὅǟ ȸη ǥǼἲ ǺǯȭǗ ǗǦĔÊĔǝǺὅǟ ǦȞǬǦὅǟ ὀǺǺǯQɘǺǣ ǗA ὀζŸǂǺǣ ǺǮĔŸʒ ȬȎȞQÊΛ ǦȞȬǣ ǦǺǗ ɉζȬǩ ɼ

.B ὀζŸǂǺǣ

Ǘ1ǼŸȬǟ) "Nitrite titration ǨΛǺQǺǟ ǥǺΛǺȞη" ɉǟζǺȞὅǟ ǨƠ ȣζὸζη ζȽ Ǻη ǼÊɰ ǦÊΛǺȬƫǟ ʔǺθ :**Assay** ǦÊΛǺȬƫǟ

Ȑƥ ȸη Ȭη 10ş ǒǺη Ȭη 75 ȸη ǰΛÂη Ž ǟǟǾǩ ǗǦĔüζǦȒη Ǧφşǟζη ǗǦǦΛǺȬǩ 0.5 ȳǟǼǺQɘǺǣ Ǘ(143 ǦȞǺȎὅǟ ǨΛǺQφ ὀζŸƮ ȸη ǺQὅ ɄŸĔη 1 Ȭȭ .VS (ὀ/ὀζη 0.1) ȳζΛǻζȎὅǟ ǨΛǺQǺǣ ǺΛǺȞΛş ǗTS (ὀ/ȟ420~) ȬΛǿζŸȭşǿǼĔƬǟ

.$C_{12}H_{13}N_4NaO_2S$ ȸη ŊŸη 30.03 ǜζǺὈΛ VS (ὀ/ὀζη 0.1) ȳζΛǻζȎὅǟ

ØØØØØ

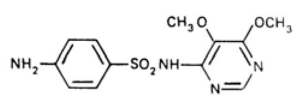
SULFADOXINUM

Sulfadoxine ǅǐƨ ǀǋǪǂƨ

$C_{12}H_{14}N_4O_4S$:**Molecular formula** ǦĔǺΛÂƨǟ ǦȣĔȎὅǟ

310.3 :**Relative molecular mass** ǦĔǦÊΛὅǟ ǦĔǺΛÂƨǟ ǦŸQὈὅǟ

:**Graphic formula** ǦĔφǺĔǦƫǟ ǦȣĔȎὅǟ



:**Chemical name** ɄǝǺĔȶĔὈὅǟ ȴɘɼǟ

N^1-(5,6-Dimethoxy-4-pyrimidinyl)sulfanilamide; 4-amino-*N*-(5,6-dimethoxy-4-pyrimidinyl)benzenesulfonamide; CAS Reg. No. 2447-57-6.

.ǦȞǝǟǺὅǟ ǨǼʒ ǗɄζǺȭ ȐĔǣǗ şǗ ɉζŸὅǟ ȐĔǣǗ ǗɃǿζŸǣ ȧζȞÊη :**Description** Ƶὸζǟ

ǗR ὀζφǺǯĔƫǟş TS (ὀ/ȟ750~) ὀζφǺǯΛqǟ Ž ɉǺǣşǾὅǟ ǴĔȞἲ ǗǒǺƫǟ Ž ǺǼǅ ɉǺǣşǾὅǟ ǴĔȞἲ :**Solubility** ǦĔφǺǣşǾὅǟ

.R ƘQɟǟ Ž ǺĔŸȶʒ ǟǟşǣ ɼ

.ǺΛǿŸƫǟ ǻǺȒη ǒǟşǻ :**Category** ǦǺǺὅǟ

Storage: [illegible]

REQUIREMENTS [illegible]

General requirement: [illegible] %99.0 [illegible] %101.0 [illegible] $C_{12}H_{14}N_4O_4S$ [illegible]

Identity tests: [illegible]

• [illegible] A [illegible] B [illegible] C [illegible] D.

A: [illegible] Spectrophotometry in the infrared region" (43 [illegible] 1) [illegible] RS [illegible].

B: 0.05 [illegible] "General identification tests" (119 [illegible] 1) [illegible].

C: 50 [illegible] 3 [illegible] (0.1 [illegible]) VS [illegible] 1.0 [illegible] (II) [illegible] (80 [illegible]) [illegible].

D: [illegible] 199 [illegible].

Heavy metals: [illegible] 1.0 [illegible] "Limit test for heavy metals" 4 (126 [illegible] 1) [illegible] A (128 [illegible] 1) [illegible] 20 [illegible].

Chlorides: [illegible] 2.5 [illegible] 30 [illegible] 10 [illegible] TS (~130 [illegible]) [illegible] "Limit test for chlorides" (121 [illegible] 1) [illegible] 0.1 [illegible].

Sulfates: [illegible] 2.5 [illegible] 40 [illegible] "Limit test for sulfates" (123 [illegible] 1) [illegible] 0.2 [illegible].

Clarity and colour of solution: [illegible] 0.50 [illegible] 10 [illegible] VS (~70 [illegible]) [illegible] Yw3 [illegible]

.(53 ǦĦǺÔöä Û1 ǼŸÕā) "Colour of liquids ÕəāζÊöä ɹζö" ɹāζȜ ǨƠ ȣζòζŋ

.ȟ/ŋŸŋ 1.0 ȡŋ ÀǯõÜ ÈĒö :**Sulfated ash** ǨǺŸÊţā ǻǺŋÀöä

ȡŋ ÀǯõÜ ǼÕǺöä ɹζǺÓ ɟ Ü°ÿ 105 ǥøāÀǵ ǦDzøǼæ ǨæǺǯöä ɹàζöä ɂøǪǵ Ƶǻƶ :**Loss on drying** ƵĒǺDzǪöǺæ ǼÕǺöä
.ȟ/ŋŸŋ 5.0

ÿ 70 ǥøāÀǵ ǦDzøǼæ R ɹζæÀÓöä ǼĒÊõÜ ȗəǺǪ ȡŋ ƃǺƪā öǺţā ȡŋ Õŋ 50 Ȝŋ ȟ 1.0 ȡǺÊÀ :**Acidity** ǦȑζȶƩā
ǼĒÊõşøǼĒö 7.0 öǺŁǺǦöä ƃÜ ǦǵǺȉÀöä ȡŋ Õŋ 25 ÀǺǺȞǺ ÜǴǹÀǺş Ü°ÿ 20 ǦDzøǼöä ƃÜ ǦȝÀÊæ ǻƎǺ ÛĘəǺęǻ 5 ǥǼŋ ǺǦǺÀÕǩ
.Õŋ 0.25 ȡŋ ÀǯõÜ ƃÜ ǦDzǺǵ õǺǺŁ ǨÊĒö ÜVS (ȯ/ȯζŋ 0.1) ÿζǺǻζÔöä

ǦÕĒęÀöä ǦÕǦÛöä ǡāÀÎǪèā" ɹāζȜ ǨƠ ȣζòζŋ ζŁ Ǻȶõ øǺǦǪǹɼā ĘǦÛǺ :**Related substances** ǦöǺÎţā ǻāζţā
15 ȡŋ ǰǺÂŋş ǦŸǨ8ŋ ǥǻǺȶõ R3 ǺÓĒŸĒÊöä ǦŋƳŁ ÿāǼǺǪèǺæ (84 ǦĦǺÔöä Û1 ǼŸÕā) "Thin-layer chromatography
10 ǦĦĒǺÔöä ɁŸȜ ŸÔǺǺŋ ĘǦÛł .õÀĦǪŋ øζÛõ TS (ȯ/ȟ17~) ǺĒǫζŋɉā ȡŋ ÿζDzǵ 3ş R ȯζǫǺǩζæ-1 ȡŋ ǺȶDzǵ
(ȯ/ȟ260~) ǺĒǫζŋɉā ȡŋ ǼǵāşǺ ǈDzǵş TS (ȯ/ȟ750~) ȯζǫǺǯǺɋā ȡŋ ÿζDzǵ 9 ȡŋ ǰǺÂŋ Ž ƙöζŸȚ ȡŋ ÀǪöşÀÓŋ
.ÀǪö ȗŸĒţā Ž RS ǼĒŋƳĒǫǺǺŸÊöä ȯζŸȚ ȡŋ ŋŸŋ 0.050 (B)ş ÀǪö ȗŸĒţā Ž øǺǦǪǹɼā ǥǻǺŋ ȡŋ ŋŸŋ 10 (A) ɃζȜ :TS
ÕĒǯĒŋ ȗəǺǪ-4 ȯζŸĦŋ æÀǨş ĘəǺęǻ 10 ǥǼŋ °ÿ 105 ǥøāÀǵ ǦDzøǼæ ȡǺÊǩ ÛǡāÀÎǪèɼā ǥÀDzǵ ȡŋ ǦĦĒǺÔöä ţÂøǫ ǼĦæ
ǦȞÕǦöä ȡŋ ǥǼȉ ÀǯõÜ ÛǦĒÊĒəÀöä ǦȞÕǦöä öǺǺǯǪèǺæ ÛA ȯζŸɉǺæ ǺȤĒŸȜ ÕÔĦǪÊǺ ǦȞÕæ ǦǺÜ ɹζÓǩ ɟ .TS3 ǼĒŁǼöäÂøǺæ ζǼŋÜ
.B ȯζŸɉǺæ ǺȤĒŸȜ ÕÔĦǪÊǺ ȗøǪöä

Û1 ǼŸÕā) "Nitrite titration ǨǺÀǪǺöä ǥÀǺǺȞŋ" ɹāζȞöä ǨƠ ȣζòζŋ ζŁ Ǻŋ ǼÊɯ ǦÊǺÕţā ʔÀθ :**Assay** ǦÊǺÕţā
Ȑþ ȡŋ Õŋ 10ş öǺŋ Õŋ 75 ȡŋ ǰǺÂŋ Ž ǡāØǩ ÛǦĒüζǦȒŋ ǦǫşàζŋÛǺǦǺÀÕǩ 0.5 ÿāǼǺǪèǺæ Û(143 ǦĦǺÔöä
ǨǺÀǪǫ ȯζŸȚ ȡŋ ÀǪö ȗŸĒŋ Õõ .VS (ȯ/ȯζŋ 0.1) ÿζǺǻζÔöä ǨǺÀǪǺæ ÀǺǺȞǺş ÛTS (ȯ/ȟ250~) ÕǺøζŸõşøǼĒŢā
.$C_{12}H_{14}N_4O_4S$ ȡŋ ŋŸŋ 31.03 ùζǺÓǺ VS (ȯ/ȯζŋ 0.1) ÿζǺǻζÔöä

øøøøø

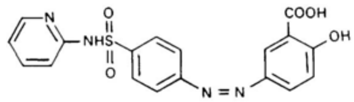
SULFASALAZINUM

Sulfasalazine DžǏŘÚƑ ƨƑƻƨ

$C_{18}H_{14}N_4O_5S$:**Molecular formula** ǦĒǺǺÂƨā Ǧ8ĒÔöä

398.4 :**Relative molecular mass** ǦĒǦÊǺöä ǦĒǺǺÂƨā ǦŸǪÓöä

:**Graphic formula** ǦĒǫǺĒǦţā Ǧ8ĒÔöä



[illegible] **Chemical name:**

5-[[*p*-(2-Pyridylsulfamoyl)phenyl]azo]salicylic acid; 2-hydroxy-5-[[4-[(2-pyridinylamino)sulfonyl]phenyl]azo]benzoic acid; CAS Reg. No. 599-79-1.

[illegible] **Other name:** [illegible] Salazosulfapyridine

[illegible] **Description:** [illegible].

[illegible] **Solubility:** [illegible] (~750 [illegible]) [illegible].

[illegible] **Category:** [illegible].

[illegible] **Storage:** [illegible].

[illegible] **Additional information:** [illegible] 255 [illegible].

REQUIREMENTS [illegible]

[illegible] **General requirement:** [illegible] %93.0 [illegible] %103.0 [illegible] $C_{18}H_{14}N_4O_5S$ [illegible].

[illegible] **Identity tests:**

- [illegible] A [illegible] B [illegible] C.

A: [illegible] "Spectrophotometry in the infrared region" ([illegible] 43 [illegible] 1). [illegible] RS [illegible].

B: [illegible] 230 [illegible] 600 [illegible] RS [illegible].

C: [illegible] 0.1 [illegible] 1.0 [illegible] (~750 [illegible]) TS 4 [illegible] (~70 [illegible]) [illegible]

[illegible] 1.0 [illegible] 5 [illegible] 0.20 [illegible] 1.0 [illegible] 1.0 [illegible] (25) [illegible] 0.1 [illegible] 2.0 [illegible] (10) [illegible] 1 [illegible] -2 [illegible] 0.1 [illegible] (80~)

[illegible] 1.0 [illegible] :**Heavy metals** [illegible] (127 [illegible] 1) 3 [illegible] "Limit test for heavy metals [illegible] 20 [illegible] (128 [illegible] 1) A [illegible].

[illegible] 70 [illegible] 100 [illegible] 2.0 [illegible] :**Chlorides** [illegible] 1 ([illegible]) [illegible] 25 [illegible] 5 [illegible] (1000~) [illegible] "Limit test for chlorides [illegible] 0.14 [illegible] (121 [illegible] 1)

[illegible] 1.5 [illegible] 25 [illegible] :**Sulfates** [illegible] 5 [illegible] 2) [illegible] 1) "Limit test for sulfates [illegible] 0.4 [illegible] (123

[illegible] 5.0 [illegible] :**Sulfated ash** [illegible]

[illegible] 105 [illegible] :**Loss on drying** [illegible] 10

Thin-layer [illegible] :**Assay** [illegible] 4 [illegible] R2 [illegible] (84 [illegible] 1) "chromatography [illegible] R [illegible] R [illegible]-1 [illegible] R [illegible] 10 [illegible] 18 [illegible] (1080) [illegible] 12 (B) [illegible] 12 (A) [illegible] :R [illegible] R [illegible] 10 (C) [illegible] RS [illegible] 15 [illegible]

ẩǍȞǤè ǯƞ ǛǨǍǛǙǨ 0.6 R_f ǦɫȄǑ ȸȁȑǍèǍǍƳÊǑ ǯǑ ʅèʐǨş (ǍǪƞʐǪǍ 254) ǦƊʐÊǍǍǦ ȧʐʐ ǦǨǐǰ ǒʐȒ ãǍǍÎǪèȑ A ǑȄǑǍǂ ȸƞ ǑǑǑ ǯǑ 3 ɃʐǪǮ ɃǾǑ ǍǑȄƳÊǑ ǦƞƳȽ ǰǍÂƞ ǑÔǍǍƞ ʐǕ ʡǛǯş ǨɫÕ ƫÂøȽ .øşǍǑ ÆǍʐÎǑ ǙǍǍì ǼȄƞǍƞøʐʐ ǑȄǯȄƞ ɄǝǍǍǪ ǑÔǶǪÊǍ ȷǕ Ǽƶ :ǦȚǵƳƞ) .ǦƊʐǍƊʐ ğǍǍǍǼè ğǍǼ ǦƳÔǍǍƞ ǑȄǍǯǨ ǼȄǍǍǪǕ ƂǕ ǍǨƳǑǍ ǛCş Bş ȑ .ƴǍǍ8Ǒ Ž ǒǍƫǍ ȸƞ ƞƳƞ 10 ȸƞ ǑȩǕ ʡǛǯ ɃʐǪǮ ȑǕ Ǽƶş ǨǯǍǼǵ Ǧǵʐ ǪǍƞ ǵøşøǍȩ ȸƞ ǦȄǑǍǪǑ ǵʐǛƪǍ Ž ƴǼǍǪÊƫǍ R Ǒõ ƂǕ R ǼȄƞǍƞøʐʐ ǑȄǯȄƞ ɄǝǍǍǪ ȸƞ Ǒƞ 10.0 ȣǍȒǍ .(ǦǍʐǛǑǑ ğǍǦȄƩǍ ʡǛǯ ȤǍǑǍ ǼȄƞǍƞøʐʐ ǑȄǯȄƞ ɄǝǍǍǪ ǑǦǑǍ ȻǼǵ Ž ʅè 1 ǦǪǍǼǯǼ ǦǑǦù Ǝǯ ȯʐǛǂǍ îǍǪ ãǍǑǍ .ʡǍÔǍ ʡøǪǵ ǑǍǯǍş ǭǝǍȩẩ 10 ǵǼƞ ʓǍǍ ǛǵǍǍǼÊǑ ǨǦǯǨ Ǜ ãʐǦǪǕ ǼÊƠ .C ȯʐǛǂǍ ȸƞ ȼȄǛǯ ǑÔǶǪÊƫǍ ǼȽǍÎǑ ɃʐǪƠ ǼǍǾƞ ǵƘƊʐǵ ǑǼǍǑƞ ǨǦǍǛǙǨ ǍǪƞʐǪǍ 406 ǦƊʐʐƫǍ ȯʐǛǼ ɄɫȚǯǰǍ .(B ȯʐǛǂǍ) RS ȸȁȑǍèǍǍƳÊǑ ǯƞ ǦǪǾǍǑƫǍǼ (A ȯʐǛǂǍ) ǾǍǦǪǹȑǍ ǵǍƞ Ž $C_{18}H_{14}N_4O_5S$ ǦȄɫÕ

ØØØØØ

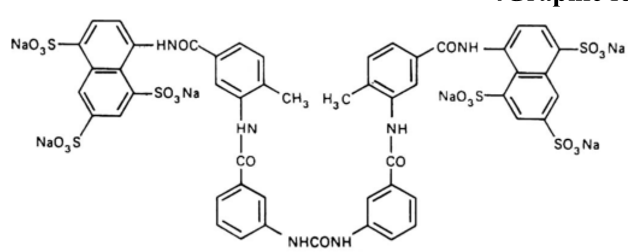
SURAMINUM NATRICUM

Suramin sodium !ǋǰǭǋȚǁǀ ǄǰǄǯƥǋƨ

$C_{51}H_{34}N_6Na_6O_{23}S_6$ **:Molecular formula** ǦȄǍǍÂƨǍ Ǧ8ȄÔǑ

1429 **:Relative molecular mass** ǦȄǦÊǍǑ ǦȄǍǍÂƨǍ ǦƳǪǑǑ

:Graphic formula ǦȄǪǍȄǦƫǍ Ǧ8ȄÔǑ



:Chemical name ɄǝǍȄɫȄǑǑ ʅèȑǍ

Hexasodium 8,8′-[ureylenebis[*m*-phenylenecarbonylimino(4-methyl-*m*-phenylene)carbonylimino]]di-1,3,5-naphthalenetrisulfonate; hexasodium 8,8′-[carbonylbis[imino-3,1-phenylenecarbonylimino(4-methyl-3,1-phenylene)carbonylimino]]bis[1,3,5-naphthalenetrisulfonate]; CAS Reg. No. 129-46-4.

.Nagananinum ƴʐǍǍǪǍƊʐǍǪ **:Other name** ǍǹǕ ʅèǍ

.ǦǶǝǍǍǑ ǋǼǯ ǕɄƩǍÕ şǕ ɄƳǍǪǍȩ ȒǍǍǕ ǛȷʐǛǑ ȒǍǍǕ ǛɃǾʐǛǍ ȧʐǶÊƞ **:Description** ȤǒʐǑ

Ž ǨȄƳɫǯ ãǍşǼ ȑ ǕTS (ȯ/ȟ750~) ȯʐǪǍǯǍǪǍ Ž ȷǍşǾǑ ǴȄǶì ǕǑǍƫǍ Ž ǨǼƊʐ ãǍşǼ **:Solubility** ǦȄǪǍşǾǑ

[illegible]

[illegible] **Category:** [illegible]

[illegible] **Storage:** [illegible]

[illegible] **Additional information:** [illegible]

REQUIREMENTS [illegible]

[illegible] **General requirement:** [illegible] 96.0% [illegible] 100.5% [illegible] $C_{51}H_{34}N_6Na_6O_{23}S_6$ [illegible]

Identity tests: [illegible]

A: [illegible] 20 [illegible] 2.0 [illegible] 1.0 [illegible] TS (~70 [illegible]) [illegible] 5 [illegible] 0.25 [illegible] TS (~10 [illegible]) [illegible] 1 [illegible] TS (~80 [illegible]) [illegible] 0.15 [illegible] 2- [illegible] TS1 [illegible]

B: [illegible] 20 [illegible] 0.10 [illegible] R [illegible] 4 [illegible] TS (~70 [illegible]) [illegible] 0.25 [illegible] 2.0 [illegible] TS (~50 [illegible]) [illegible]

C: [illegible] 0.05 [illegible] 2.0 [illegible] 0.25 [illegible] B [illegible] "General identification tests [illegible]" [illegible] 1 [illegible] 123 [illegible]

Heavy metals: [illegible] 1 [illegible] "Limit test for heavy metals [illegible]" 3 [illegible] 1 [illegible] 127 [illegible] A [illegible] 1 [illegible] 128 [illegible] 20 [illegible]

Chlorides: [illegible] 0.5 [illegible] 10 [illegible] 5 [illegible] TS (~130 [illegible]) [illegible] 5 [illegible] VS (0.1 [illegible]) [illegible] 3 [illegible] R [illegible] VS (0.1 [illegible]) [illegible] 2 [illegible] TS (45 [illegible]) [illegible] VS (0.1 [illegible]) [illegible] 3.6 [illegible]

ÛTS (ȯ/ȟ250~) ǑǺǿǫŸǒşǿǼŒŦǟ Ȑ ƥ ȸȠ Ǒȵ 3 ȣǺȐǺ ÛǒǺȵ Ǒȵ 20 Ž ȟ 0.50 ǡǟǾǺ :**Sulfates** ǧǺǺŸÊǒǟ ǦǶǺÔǒǟ Û1 ǼŸÖǟ) "Limit test for sulfates ǧǺǺŸÊǒ ǑǅƗ ɃǼΣǟ ǿǺǬȵȑǟ" ȷǟǫǺȝ ƘƠ ȣǫȍǫȵ ǫȽ Ǻƚǒ ȝǟǺǬş .ȟ/ȠŸȵ 1 ȸȝ ǧǺǺŸÊǒǟ ʔǫǬȚ ǼǺÂǺ ȑ Ü(123

ǼŒÊǒÜ ɄǝǺǺǭ ȸȠ ƃǺȘǟ ǒǺƫǟ ȸȠ Ǒȵ 10 Ž ȟ 0.50 ÂŒǒÀǬǟ ȯǫŸȚ ȷǫȮǺ :**Clarity of solution** ȯǫŸǂǟ ǒǺÀȍ .ǺŒǫǺȍ ȷǫǟÀȮǒǟ

Determination of water by ÀÎŒǫ ȯǿǺǒ ǦǑǺÀÛǟ ǒǺƫǟ ƙŒȞǨ" ȷǟǫǺȝ ƘƠ ȣǫȍǫȵ ǫȽ Ǻƚǒ ȸǺȞǺ :**Water** ǒǺƫǟ ʔǫǬȚ ǼǺÂǺ ȑ ÜǺǦǺÀǑǨ ǥǻǺƫǟ ȸȠ ȟ0.2 ȳǟǼǺǬȅǺǟ Û(145 ǦǶǺÔǒǟ Û1 ǼŸÖǟ) A ǦǑǺÀÛǒǟ Û"the Karl Fisher Method .ȟ/ȟ 0.10 ȸȝ ǒǺƫǟ

.7.0-5.5 ÛR ȷǫǟÀȮǒǟ ǼŒÊǒÜ ɄǝǺǺǭ ȸȠ ȯǺȵ ǒǺȵ Ž Ǒȵ/ȠŸȵ 10 ÂŒǒÀǬǟ ȯǫŸȚ ǒǺȽǺǦǒǟ ǦƚŒȩ :**pH Value**

0.1) ǑǺǿǫŸǒşǿǼŒŦǟ Ȑ ƥ ȸȠ Ǒȵ 30 ȣǺȐǺş ǒǺȵ Ǒȵ 30 Ž ȟ 5 ǡǟǾǺ :**Free amines** ǥÀΣǟ ǧǺǺŒȵƗǟ ǼǺȝ ǺŦǬǺŒ ǦÛǑǭ ǥǺǺǨƫǟ ȠŸǦǨ .R ǼǺǻǫŒǒǟ/ǺÎǺǒǟ Ǧȩǿş ʔŸȝ ȧǿǟÜ ȷǫǒ ȷǬǺ ʔǿǬǵ ÛǥǫǑǟ ǑǺÀǶǬǒǟ ȝȵ ÛVS (ȯ/ȯǫȵ ɄǝǺǟÀŦȮǒǟ ȃǺŒǑǟ ǦǑǺÀÛǟ ǥǺǺǨƫǟ ǒǟÀǅÜ ȸȮƺ .ǦǑŒȩǻ ǥǼȵ ǿǟÀǑǬȅŸǒ ǥǺǺǨƫǟ ȯǫŸȚ ǑǺǨ ǼǨǟ ȧǿȁƗǟ ȷǫŸǒǟ ǑȮÎǨ ǥǻǫȝ .Ǒȵ 0.4 ȁşǺǅǫǬǺ ȑ ƙǨǺǺǨƫǟ ƙǟ ȴǅΣǟ ȧÀǫ .ǿǺǬȵȑǟ ǥǻǺȵ ȷşǻ ǦŒŸƚǨǒǟ ǻǺǨǨ .electrometrically

ǦǺǿǾǟ infected ǦǼǼǨƫǟ ȷǟÀǺǺǒǟ ʔŸȝ ǦǼǨǒǟ ƎǬƠ ÛǦŒǅƳǨǒǟ ǦŒŸȝǺǺŸǒ :**Therapeutic potency** ǦŒǅƳǨǒǟ ǦŒŸȝǺǺǒǟ ƙȠǟǿǫÊǒ ǦȅǺÊΣǟ ǧǺŒǦǑǯƫǟ ȸȠ ǦƚəƳƫǟ ʔÀȵƗǟ ƫǟǫǬƗǟ şÜ ÛTrypanosoma equiperdum ǥǺƚÊƫǟ ǧǺŒǦǑǯƫǟ ǿǖǫ Ǒǒ ȳǻ ȌǶǺǺ ǦȝǺȅ 48 ǼǨǟ .ǧǺŒǦǑǯƫǺǟ Ǒȩƚǟ ʔŸȝ ȷǟÀǺǫ 10 ǴǑŸǺ :ɄŸǺ Ǻƚǒ ǿǺǬȵȑǟ ǒǟÀǅÜ ȸȮƺ .ȳǫǺǻǫȍ ǒǟÀǅÜ ȸȮƺ .20 000ş 1000 ƙǟ ȴȩÀǒǟ ǳşǟÀǬǺ ȷÜ ǼƵ .ǿǖǫ Ǒǒ ȳǻ ȸȠ ÀǬǒ ɄŸŒƫǟ Ž ǧǺŒǦǑǯƫǟ ǻǼȝ ǿǺǼǑǺş ǺǺÀŦƒ ʔŸȝ ǧǺŒǦǑǯƫǟ ǼȝşÛcover-slip preparation ǥǺǨǺȍ ȝȵ ÀȐǶǬÊȵ ǑȮȉ ʔŸȝ ȳǼǒǟ ȸȠ ǤŒȩǿ ȴŸǫ ȌǶǺǟ ÀǺǼǑǬǒǟ ȸȠ Ǒǒǵ Ǒǒ Ž ǦŒǦǑǯȵ 20 ƃÜ 1 ǻǫǅş ǤǫǟǫǬǺ .Ǒȩƚǟ ʔŸȝ 2ȴŸȵ 0.12 ǺŦǺȵ Ǒǒ ǦǵǺÊȵ ǦǺÀŦƒ ȯǫǑǵ 10 Ž Ǒȩƚǟ .ǺǦǺÀǑǨ ÀǬǒ ɄŸŒƫǟ Ž ǦŒǦǑǯȵ 20 000 ƃÜ 1000 ʔǫǬȚ ȝȵ ƙŸǑǵ

ǑȮǒ ǺǅǫȁǺȕ ÀÛǑȵ ǒǺȵ Ž ǦǼǨǒǟ ȸȠ ȯ/ȠŸȵ 50 ÂŒǒÀǬǟ ȯǫŸȚ ȸȠ Ǒȵ 0.16 ǿǟ ÛǺǺǼǺǿş ÛǦǺǼǨȵ ȷǟÀǺǫ 10 ȸǑƠ ȳǫŒǒǟ Ž ÛȴŸȵ objective-4 (ǦȅǼȝ) ǦŒǺȉ Ƀǟ ÀŦƒ ȳǟǼǺǬȅǺǟ ÛǺÀŦƒ ǿǖǫ Ǒǒ ȳǻ ȌǶǺǺ .ȴÊƨǟ ǦŸǬǒ ȸȠ ȳǟÀȡ ÛǬǒǺǯǒǟ ȳǫŒǒǟ Ž ǻŸǑǵ 20 ȌǶǫ ǼǺȝ ȷǟÀǺǺǒǟ ȸȠ ÀǯǒÜ şÜ 5 ȳǻ Ž ǧǺŒǦǑǯȵ ǼǅǫǨ Ɓ ǟǽÜ .ȸǑΣǟ ǼǨǟ ǬǒǺǯǒǟş ȯşƗǟ ǻǺǨǺ ÛȷǟÀǺǫ 5 ȸȠ ÀǯǒÜ ȳǻ Ž ǦǑǟǺÊǒǟ ȓşÀÎǒǟ Ǒș Ž ǧǺŒǦǑǯƫǟ ǧǼǅş ǟǽÜ .ǿǺǬȵȑǟ ǧǟǺǬǅǟ ǼȩǦǼǨǒǟ ȷǫȮǨ ȷǟÀǺǺŸǒ ƃǺƤǭǟ ǻǼǨǒǟ ȸȠ %50 ȳǻ Ž ǦǑǟǺÊǒǟ ȓşÀÎǒǟ Ǒș Ž ǦŒǦǑǯȵ ǦǺÜ ǼǅǫǨ Ɓ ǟǽÜ ǿǺǬȵȑǟ ǦǼǨǒǟ ǟǺǬƟ .ǿǺǬȵȑǟ .Ǒȩƚǟ ʔŸȝ ǦƨǺǨƫǟ

ÛTS (ȯ/ȟ700~) ÕƖǿźȦŸÊǖ Ȑƥ ȡŋ Ǒŋ 12 ÛǦŀùźĜȒŋ ǦǫȿàźŋÛǊǖÄǑǩ ȟ 0.5 БǗ ȢȦȒƖ :**Assay** ǦÊƖǕţǟ ÆŀŋȿÄǣ ȡŋ ȟ 1 ȢȦȒƖ .ǒȦţǞ Ǒŋ 100 ǦǟǟÄȩ БǗ ƵȦƸȿ ǻƎƖ ÜǦȝȦè ǥÆŋ ȾȝźǅǛÄǟ ȷȦȦÄƨǞ ǑȶȞƖ ƵǰǑŋ ǨƠ ʔŸȣƖȿ ʔøǪǵ ǥźǕǞ ÕƖÄǶǪǟ Ȝŋ ÛVS (ȯ/ȯźŋ 0.1) ȳźƖǻźÔǖ ǨƖÄǪǞ °ȳ 20ȿ 15 ƙǞ ǥøǟÄǵ ǦǅźøÆǞ ÄȦȞƖȿ R ȳźŀèȦǩźǦǖ ȯźŸȚ ǒÄǩ ÆȞǞ ȧøàɉǟ ȷźŸǖ ǑȮÎǩ ǥǻźȝ ÆƖȝ ȦȚǪƖŒ ǦÛǑǫ ǥÄȦȞţǟ ŋŸǦǩ .R ÆƖǻźŀǖ/ȦÎƖǖ Ǧęøȿ ʔŸȝ ȧøàǗ ȷźǒ ǰǪƖƖ .øȦǦǪǹɍǟ ǥǻȦŋ ȷȿǻ ǦŀŸȶȞǖ ǻȦȞǩ .ȾǝȦǞȚȮǖ ȃȦŀǕǖ ǦǑƖÄÛǞ ǥÄȦȞţǟ ǒǟÄǅǗ ȡȮź .ǥÆǥǟȿ ǦǑŀęǻ ǥÆŋ øǟÄǕǪèɎǒ ǥÄȦȞţǟ

.$C_{51}H_{34}N_6Na_6O_{23}S_6$ ȡŋ ŋŸŋ 23.82 ùźȦȮƖ VS (ȯ/ȯźŋ 0.1) ȳźƖǻźÔǖ ǨƖÄǪǫ ȡŋ ÄǪǒ ȾŸŀŋ ǑÕ

ØØØØØ

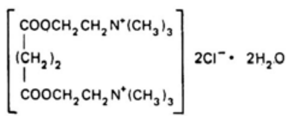
SUXAMETHONII CHLORIDUM

Suxamethonium chloride !ǋǏǆǋǨǏǅǷ ƨ ǀǷ ƨ ǁǁ ǫǏƥǋǂǀ

$C_{14}H_{30}Cl_2N_2O_4,2H_2O$:**Molecular formula** ǦŀȦȦÂƨǟ ǦȢŀÔǖ

397.3 :**Relative molecular mass** ǦŀǦÊƖǖ ǦŀȦȦÂƨǟ ǦŸǪȮǖ

:**Graphic formula** ǦŀǫȦŀǦţǟ ǦȢŀÔǖ



:**Chemical name** ȾǝȦŀȶŀȮǖ ȴèɍǟ

Choline chloride, succinate (2:1), dihydrate; 2,2′-[(1,4-dioxo-1,4-butanediyl)bis(oxy)]bis[*N*,*N*,*N*-trimethylethanaminium] dichloride, dihydrate; 2,2′-succinyldioxybis(ethyltrimethylammonium) dichloride, dihydrate; CAS Reg. No. 6101-15-1(dihydrate).

.Succinylcholine chloride ƙǒźÕ ǑŀÆŀÊȮÊǖ ÆƖǿźŸÕ :**Other name** ÄǹǗ ȴèǟ

.ǦƖÄǑǩ ǦȞǝǟÄǖ ǄÆȝ ȿǗ ǦȞǝǟÄǖ ǄÆȝ ÜǦƖÄǑǩ ȐŀǞǗ ȿǗ ȷźŸǖ ȐŀǞǗ ÛɃøźŸǞ ȧźȞÊŋ :**Description** Ƶòźǖ

ǟȦȿǽ ɍ ÜTS (ȯ/ȟ750~) ȯźǫȦǰƖɋǟ Ž ȷȦǞȿØǖ ǴŀȞȉ ÜǒȦţǟ ȡŋ ÆǵǟȿǒÄǅ Ž ǟȦȿǽ :**Solubility** ǦŀǫȦǞȿØǖ

.R ƘǪɉǟ Ž ȦŀŸȶȝ

.ȾŸȒȝ ƿÄŋ :**Category** ǦȦÄǖ

.ǒźȒǖ ȡŋ ʔȶȞɫ ȷǗȿ ÛŀÆŀǅ ǦǑŸȢŋ ǦƖȿȦǵ Ž ȳźŀǫźǰŀŋȦÊÕȦÊǖ ÆƖǿźŸÕ ȘȦȜ ȷǗ Æƶ :**Storage** ȡȦÂǺǪǖ

ÆƖȝ ǰƖøÆǪǒȦǞ ǒǿÆǪƖ .ǦǦùÄǪÊŋ ǥǻȦŋ ȳźŀǫźǰŀŋȦÊÕȦÊǖ ÆƖǿźŸÕ :**Additional information** ǦŀźȦȓǗ ǧȦŋźŸȞŋ

[illegible].

REQUIREMENTS [illegible]

General requirement [illegible] 98.0% [illegible] 101.0% [illegible] $C_{14}H_{30}Cl_2N_2O_4$ [illegible].

Identity tests [illegible]:

A: [illegible] 25 [illegible] 1 [illegible] 0.1 [illegible] (II) [illegible] (5/[illegible]) TS [illegible] 0.1 [illegible] (45/[illegible]) TS [illegible].

B: [illegible] 0.05 [illegible] 10 [illegible] 10 [illegible] (~100/[illegible]) TS [illegible] 30 [illegible] ammonium reineckate (10/[illegible]) TS [illegible] 30 [illegible] (~750/[illegible]) TS [illegible] R [illegible] 80 [illegible] 183 [illegible].

C: [illegible] 0.05 [illegible] A [illegible] "General identification tests" [illegible] (1 [illegible] 121).

Clarity and colour of solution [illegible] 1.0 [illegible] 10 [illegible].

Sulfated ash [illegible] 1.0 [illegible].

Water [illegible] "Determination of water by the Karl Fisher Method" [illegible] A (1 [illegible] 145) [illegible] 0.15 [illegible] 80 [illegible] 100 [illegible].

pH Value [illegible] 10 [illegible] 4.0-5.0.

Related substances [illegible] "Thin-layer chromatography" (1 [illegible] 84) [illegible] R2 [illegible] 4 [illegible] 1-[illegible] R [illegible] (300/[illegible]) TS 5 [illegible] 10 [illegible] (A) 5.0 [illegible] (B) 0.10 [illegible]

ǦDZǿǼǣ ǫȦƟ Ûāȁ ȦÎǫèɍǟ ǵȦDzǵ ȡŋ ǦƜǼȦÔöä ƫÂøƥ ǼǨǣ .Ǧʒȧè 2½ ǵǼŋ ǦƜǼȦÔöä ȦǮȚǨ .ȦǪö ɄŸƗƫǟ Ž ǿȦǪǹɍǟ Ž āȁȦÎǫèǟ ÙÛƯ ÒƜȦȘ TS2 ȳǫƗèȦǩǫǦöä ǧȦȦƗŸǣşȧǫȦ ȯǫŸƜŋ ǣȦǨ ÛǻƎǪö ȭȦǪǩ ÛǦÕƗęǻ 15 ǵǼŋ °ȳ 90 ǵǿȁȦǵ ɄøǪöä ǦǨÕǦöä ȡŋ ǵǼì ȦǯõÜ ÛǦƗÊƗǝȦöä ǦǨÕǦöä ǿȦǯǪèȦǣ ÛA ȯǫŸǂȦǣ ȦǮƗŸʒ ŌÔƜǪÊȦ ǦǨÕǣ ǦȦÜ ȷǫȮǨ ɍ .ǿȦǮȦöä ȭǫȑ .B ȯǫŸǂȦǣ ȦǮƗŸʒ ŌÔƜǪÊȦ

30 ȣȦȒȦ ÛR1 ɄDzŸǯöä ÕƗǪèɉǟ Ȑƥ ȡŋ Ōŋ 30 Ž ÛǦƗüǫǦȒŋ ǦǫşàǫŋÛȟ 0.3 Ǧǣȁȩ āȁǾƚ :**Assay** ǦÊȦȦÕƫǟ Ȑƥ ʒŋ ȦȦǨȘ ÛTS ÕƗǪèɉǟ Ȑƥ/ÕƗÕǦǝȦöä ǧȦǪƗèÜ ȯǫŸȚ ȡŋ Ōŋ 10ş R ÕƗǪèɉǟ ǼȦǿǼƗŒÜ ȯǫŸȚ ȡŋ Ōŋ Û"Non-aqueous titration ɄǝȦŋŸöä Ùèǫöä Ž ǵȦȦǨƫǟ" ȷȁǫȦʒ ǨƠ ȣǫȯǫŋ ǫȽ ȦƫõVS (ȯ/ȯǫŋ0.1) ÕȦǿǫŸõǨǦöä ȡŋ ŊŸŋ 18.07ùǫȦÒȦ VS (ȯ/ȯǫŋ 0.1) ÕȦǿǫŸõşǨǦöä Ȑƥ ȡŋ Ōŋ 1 Ōõ .(142 ǦƜȦÔöä Û1 ǼŸÕǟ) A ǦÕȦȦÛöä .$C_{14}H_{30}Cl_2N_2O_4$

ǰǳşƟ üǱDŽƴƚƨŰƐ üƜŬ !ǆǏǳǆǨǏDŽǱƨ ǀǱƨǁƐ ǫǏþǆǂǀǁ ȟǏǯǱȚǟ ǀǱǂƯƗDŽ

Additional Requirements for Suxamethonium chloride for parenteral use

.(56 ǦƜȦÔöä Û4 ǼŸÕǟ) "*Parenteral preparations* ǦƗÕΣǟ ǧȁȦȒƜǪÊƫǟ" ǵǻşȦǫɉ ǼƗDzǪÊȦ

ǿȦǪǹɍǟ" ȷȁǫȦʒ ǨƠ ȣǫȯǫŋ ǫȽ ȦƫõǿȦǪǹɍǟ ĘǦÛȦ :**Bacterial endotoxins** ǦƗŋǫǪȦƨǟ ǦƗŸǹȁǼöä ǧȦǥȦȦǾöä 30 ǦƜȦÔöä ÛǦȦÂƗŸȮǥqǟ ǦǨǦÛöä Û5 ǼŸÕǟ) "Test for Bacterial endotoxins ǦƗŸǹȁǼöä ǦƗŋǫǪȦƨǟ ǧȦǥȦȦǾöä ŌDZɉ .ȳǟȦȡ ɄŸƗƫǟ Ž ǦƗöşǻ ǵǼǵş 2.0 RS ɄŸǹȁǼöä ȷȦȦǾöä ȡŋ ʔǫǪǂǟ ȁşȦDzǪȦ ɍ Û(ǦȦÂƗŸȮǥqǟ ǦǨǦÛöä

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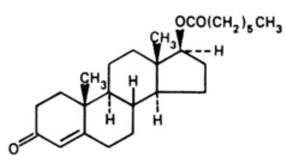
TESTOSTERONI ENANTAS

Testosterone enantate DŽǆþǏƚƨǆƚƨǁƐ ǀƗǳǱǳǏǟ

$C_{26}H_{40}O_3$:**Molecular formula** ǦƗȦȦÂƨǟ Ǧ8ƗÔöä

400.6 :**Relative molecular mass** ǦƗǦÊȦöä ǦƗȦȦÂƨǟ ǦŸǪÒöä

:**Graphic formula** ǦǥȦƗǦƫǟ Ǧ8ƗÔöä



:**Chemical name** ɄǝȦƗƚƗÒöä ȴèɍǟ

Testosterone, heptanoate; 17β-[(1-oxoheptyl)oxy]androst-4-en-3-one; CAS Reg. No. 315-37-7.

Description [illegible]: [illegible].

Solubility [illegible]: [illegible] (~750) [illegible] TS [illegible] R [illegible].

Category [illegible]: [illegible].

Storage [illegible]: [illegible] 15 °[illegible].

Additional information [illegible]: [illegible] 37 °[illegible].

REQUIREMENTS [illegible]

General requirement [illegible]: [illegible] 97.0% [illegible] 103.0% [illegible] $C_{26}H_{40}O_3$ [illegible].

Identity tests [illegible]:

• [illegible] A [illegible] B [illegible] C.

A: [illegible] "Spectrophotometry in the infrared region" (43 [illegible] 1 [illegible]). [illegible] RS [illegible].

B: [illegible] "Thin-layer chromatography" (84 [illegible] 1 [illegible]) [illegible] R1 [illegible] 10 [illegible] R 90 [illegible] 5 [illegible] 16 [illegible] 4 [illegible] 6 [illegible] R [illegible] (A): R [illegible] 9 [illegible] 2 [illegible] 1.0 (B) [illegible] 1.0 [illegible] RS [illegible] 12 [illegible] 120 °[illegible] 10-5 [illegible] 4-[illegible] TS [illegible] 120

[illegible] (365 [illegible]) [illegible] 10 [illegible]
.B [illegible] A [illegible]
:[illegible] 293 [illegible]
Related [illegible]
."substances

[illegible] TS [illegible] 1760~) [illegible] 2.0 [illegible] 5 [illegible] :C
[illegible] TS [illegible] 750~) [illegible]
[illegible]

[illegible] 10 [illegible] :**Specific optical rotation** [illegible]
$.[a]_D^{20°C} = +77 \text{ to } +83° R$

[illegible] :**Loss on drying** [illegible]
5.0 [illegible] 5 [illegible] 0.6 [illegible]
[illegible]

[illegible] 10 [illegible] 0.5 [illegible] :**Free heptanoic acid** [illegible]
[illegible] TS [illegible] TS [illegible] 750~)
[illegible] 0.6 [illegible] TS [illegible] VS [illegible] 0.01)
[illegible] VS [illegible] 0.01) [illegible]

[illegible] :**Related substances** [illegible]
92 [illegible] R1 [illegible] (84 [illegible] 1 [illegible]) "Thin-layer chromatography
[illegible] 0.5 [illegible] R [illegible] 8 [illegible] R [illegible]
(A) [illegible] :R [illegible] R [illegible] 9 [illegible] 5 [illegible]
[illegible] 0.20 (B) [illegible] 20
[illegible] 10 [illegible] 110 [illegible]
[illegible] 10 [illegible] 110 [illegible] TS [illegible]
[illegible] A [illegible] (365 [illegible])
.B [illegible]

[illegible] 100 [illegible] R [illegible] 20 [illegible] :**Assay** [illegible]

[illegible] 1 [illegible] 100 [illegible] 5 [illegible] $C_{26}H_{40}O_3$ [illegible] 241 [illegible] 10 [illegible] RS [illegible] ± 0.42 [illegible] R [illegible] RS [illegible] 0.02.

[illegible]

Additional Requirements for Testosterone enantate for parenteral use

[illegible] "*Parenteral preparations*" [illegible] (56 [illegible] 4 [illegible]).

[illegible] **Bacterial endotoxins** [illegible] "Test for Bacterial endotoxins" [illegible] (30 [illegible] 5 [illegible]) [illegible] 3.5 RS [illegible].

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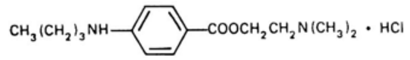
TETRACAINI HYDROCHLORIDUM

Tetracaine hydrochloride [illegible]

[illegible] **Molecular formula:** $C_{15}H_{24}N_2O_2,HCl$

[illegible] **Relative molecular mass:** 300.8

[illegible] **Graphic formula:**



[illegible] **Chemical name:**

2-(Dimethylamino)ethyl *p*-(butylamino)benzoate monohydrochloride; 2-(dimethylamino)ethyl 4-(butylamino)benzoate monohydrochloride; CAS Reg. No. 136-47-0.

[illegible] **Other names:** [illegible] Amethocaine [illegible] Dicainum.

[illegible] **Description:** [illegible].

[illegible] **Solubility:** [illegible] 8 [illegible] (750~) TS [illegible] R [illegible] R.

.ƟĤȓ ƺƞ ǿǺƯ :**Category** ǦÂÀöä

.ŏƺȒöä ʥƞ ʔȶĦł ȷǕş ÛÿȦÒǵüæ ǦŎŸ8ƞ ǦȦşȦǵ Ž ƙəȦõäȦǪöä ǼȦǿƺŸõşǿǼĿ ȘȦȜ ȷǕ Ǣƶ :**Storage** ʥȦÂǺǪöä

ǸŸǫ Ȧƞ ǈĤù ¢ö ÜĞĞùȦǪÊƞ ǥǻȦƞ ƙəȦõäȦǪöä ǼȦǿƺŸõşǿǼĿ :**Additional information** ǦĿƺȦȓǕ ğȦƞƺŸĤƞ
ÛöƺȒöä āȦǼ8æ ʔǿǪǵ ÛǢùȦöä ƺDzŸö ¢ȓȦĤǩ ǼȦȜ ǰȦǿǼǪöȦæ ǭǿǼǪȦ .ȷȦÊŸöä ʔŸȝ ¢Ĥȓş ʔǼö ǸĤȓƺƞ ǸŸŸ ǢǦÊȦş
.ǦĤȦǩȦƫä ǥǿäȦΣä ğȦDzǿǻ Ž ƫȦèǕ ȭÒȦǪöä ǴǦÔȦş

ȦƵǼǵǕ ÛƙȦŸǪƯ ƙŸÒì ǼǵǕ Ž ǼDzƺȦ ȷǕ ʥÒƺ şǕ ǨȦȦŎǩ °ÿ 134 ǥǿäȦǵ ǦDzǿǼæ ƙəȦõäȦǪöä ǼȦǿƺŸõşǿǼĿ ȦƬÔȦȦ
.°ÿ 147-134 ȯȦÕä Ž ƙŸÒÎöä ǰȦÂƞ ȦƬÔȦȦ .°ÿ 139 ǥǿäȦǵ ǦDzǿǼæ Ȧņǿäş °ÿ 134 ǥǿäȦǵ ǦDzǿǼæ ȦƬÔȦȦ

REQUIREMENTS ƘǦŀȨƟƙdž!ƒ

ǼȦÂȦ ɍş %98.0 ʥȝ ȬȪȦ ɍ Ȧƞ ʔŸȝ ƙəȦõäȦǪöä ǼȦǿƺŸõşǿǼĿ Ƀƺǫȝ :**General requirement** ÿȦĤöä ǢŸÛǪƫä
.ǦÂÀÕä ǥǻȦƫä ɃǕ ƫƺDzȦöȦæ ǦæƺÊƮ Û$C_{15}H_{24}N_2O_2,HCl$ ʥƞ %101.0 ʥȝ

:**Identity tests** ƕĭǊǊǁ ǃ ɛƥƑǶƠɛ

ʔŸȝ ǦæȦèȦöä ȝȶθ .TS (ȯ/ȟ75) ÿƺǪƺƞȷä ğȦǼèƺǪ ʥƞ Ȭƞ 1 8ȦȒȦş ŏȦƞ Ȭƞ 10 Ž ȟ 0.2 āäǾȦ :A
.°ÿ 131 ǦäȦǫ ÛǿȦƬÔǪɍä ǦDzǿǻ ÜƙǪȝȦè ǥǼƞ °ÿ 80 ǥǿäȦǵ ǦDzǿǼæ ƸȦΘş ÛöȦƫä ʥƞ ǥǿƺŸǦöä ǻȦĤǩ ÛǴìȦƞ
General ǦƞȦĤöä 8äȦĤǪèɍä ğäǿȦǪǹä" ȷäƺȦȝ ǨƠ 8ƺòƺƫä A ȬȝȦÂǪöä Ȭƞ/ƞŸƞ 20 ȯƺŸƮ ƟÛĤȦ :B
.(121 ǦĦȦÔöä Û1 ǼŸŎä) ğäǼȦǿƺŸÒŸö ÂǼȶȶõ "identification tests

ɃȦƪä ŏȦƫä ʥƞ Ȭƞ 10 Ž ȟ 0.20 ÂǼõȦǪæ ȯƺŸƮ ȷƺÒȦ :**Clarity and colour of solution** ȯƺŸǂä ȷƺǿş ŏȦÂÔöä
.ȷƺŸöä ƇǼȝş ǸƺȦò R ȷƺæȦÒöä ǼǼÊõǕ ƟəȦǪ ʥƞ

.ȟ/ƞŸƞ 1.0 ʥƞ ȦǯõǕ ȄǼö :**Sulfated ash** ǨȦŸÊƫä ǻȦƞȦöä

ʥƞ ȦǯõǕ ǼȬȦöä ȷƺÒȦ ɍ Ü°ÿ 105 ǥǿäȦǵ ǦDzǿǼæ ǨæȦǯöä ȷäƺöä ʔǿǪǵ Ƹȧƶ :**Loss on drying** ƸǼȦDzǪöȦæ ǼȬȦöä
.ȟ/ƞŸƞ 10

.6.0-4.5 ÛR ȷƺæȦÒöä ǼǼÊõǕ ƟəȦǪ ʥƞ ȯȦǹ ŏȦƞ Ž Ȭƞ/ƞŸƞ 10 ÂǼõȦǪæ ȯƺŸƮ ŏȦĿȦæ :**pH Value** ŏȦĿȦǦöä Ǧȶǫ
ǦŎǼǫȦöä ǦȪǦÛöä āäȦÎǪèä" ȷäƺȦȝ ǨƠ 8ƺòƺƞ ƺĿ Ȧȶõ ǿȦǪǹɍä ȨǦÛȦ :**Related substances** ǦŏȦÎƫä ǻäƺƫä
80 ʥƞ ǰȦƞş ǦŸ8ƞ ǥǻȦȶõ R4 ȦÒǼŸÊöä ǦƞŸŁ ÿäǼǺǪèȦæ (84 ǦĦȦÔöä Û1 ǼŸŎä) "Thin-layer chromatography
ǿƺÛõ R ƟDzŸǯöä ȬǼǪèȷä Ȑƥ ʥƞ ÿƺDzǵ 4ş ÛR ȷȦÊÒǼƬä ʥƞ ǸȶDzǵ 16ş R ƘǪȷä ȬǼǩƺæ ƟəȦǪ ʥƞ ǸȶDzǵ
12 ƫȦǩǿä ɃǕ ǢȦǾƫä ȯƺòş ǼĤæ .ǨȦȦŎǩ ȬəȦÊöä Ž ǈŸƞ 5 ȦƬÊǼÛ8æ Ûāäȝ ȦÎǪèɍä ǥȦDzǵ Ž ǦĦǼȦÔöä ȝȓƺǩ .õȦĦǪƞ

[illegible] 0.050 (B) [illegible] 0.10 (A) [illegible] 5 [illegible] 10 [illegible] R [illegible]-4 [illegible] 10 [illegible] 105 [illegible] 254) [illegible] B [illegible] (B [illegible]).

Assay [illegible] "Nitrite titration [illegible]" (1 [illegible]) [illegible] 0.5 [illegible] (143 [illegible] 50 [illegible] 5 [illegible] (0.1 [illegible]) VS [illegible] 1 [illegible] TS (~420 [illegible]) [illegible] (0.1 [illegible]) VS [illegible] 30.08 [illegible] $C_{15}H_{24}N_2O_2,HCl$.

[illegible]

Additional Requirements for Tetracaine hydrochloride for parenteral use

Test for non-injectable [illegible] "*preparations*" (5 [illegible] 32 [illegible]).

ØØØØØ

THIAMINI HYDROBROMIDUM

Thiamine hydrobromide [illegible]

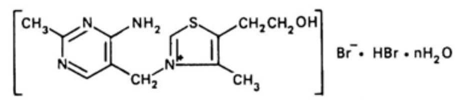
Thiamine hydrobromide, anhydrous [illegible]

Thiamine hydrobromide, hemihydrate [illegible]

Molecular formula [illegible]: (anhydrous [illegible]) $C_{12}H_{17}BrN_4OS,HBr$ ([illegible]) (hemihydrate $C_{12}H_{17}BrN_4OS,HBr,½H_2O$.

Relative molecular mass [illegible]: 426.2 [illegible] 435.2 [illegible].

Graphic formula [illegible]:



n = 0 (anhydrous)
n = 1/2 (hemihydrate)

Chemical name [illegible]:

Thiamine bromide, monohydrobromide; 3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methylthiazolium bromide, monohydrobromide; CAS Reg. No. 4234-86-0 (anhydrous).
Thiamine bromide, monohydrobromide, hemihydrate; 3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methylthiazolium bromide, monohydrobromide, hemihydrate; CAS Reg. No. 62084-87-1 (hemihydrate).

Description [illegible]: [illegible].

Solubility [illegible]: [illegible] (~750) [illegible] R [illegible].

Category [illegible]: B [illegible].

Storage [illegible]: [illegible].

REQUIREMENTS [illegible]

General requirement [illegible]: [illegible] %98.0 [illegible] %101.0 [illegible] $C_{12}H_{17}BrN_4OS,HBr$ [illegible].

Identity tests [illegible]:

A: [illegible] 10 [illegible] 1 [illegible] 1 [illegible] 0.5 [illegible] (~80) [illegible] (10) [illegible] 5 [illegible] R [illegible]-2 [illegible] 10-5 [illegible]-2 [illegible] (365 [illegible]) [illegible].

B: [illegible].

C: [illegible] 20 [illegible] A [illegible] "General identification tests" [illegible] (1 [illegible] 120).

Heavy metals [illegible]: [illegible] 1.0 [illegible]

1 (127) "Limit test for heavy metals" A (128) 20

10 0.6 :Clarity and colour of solution

1.0 :**Sulfated ash**

105 °C :**Loss on drying** 5.0 25

3.4-2.7 0.06 :**pH Value**

10 30 0.30 :**Assay** 0.1 VS (142) A "Nom-aqueous titration"

$C_{12}H_{17}N_{4}BrOS,HBr$ 21.31 0.1 VS 1

ØØØØØ

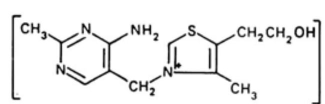
THIAMINI HYDROCHLORIDUM

Thiamine hydrochloride

$C_{12}H_{17}ClN_4OS,HCl$:**Molecular formula**

337.3 :**Relative molecular mass**

:**Graphic formula**



:**Chemical name**

Thiamine chloride, hydrochloride; 3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methylthiazolium chloride, mono-hydrochloride; CAS Reg. No. 67-03-8.

:**Description**

[illegible] **Solubility**: [illegible] 100 [illegible] 100 [illegible] (~750 [illegible]) TS [illegible]
[illegible] R [illegible] R.

[illegible] **Category**: [illegible] B.

[illegible] **Storage**: [illegible]

[illegible] **Additional information**: [illegible] 4 [illegible] 100 [illegible] 284 [illegible] 4.0 [illegible]

REQUIREMENTS [illegible]

[illegible] **General requirement**: [illegible] %98.0 [illegible]
%101.0 [illegible] $C_{12}H_{17}ClN_4OS$, HCl [illegible]

Identity test [illegible]

A: [illegible] 10 [illegible] 1 [illegible] 1 [illegible] 1 [illegible] (~80 [illegible]) TS 0.5 [illegible]
(10 [illegible]) TS [illegible] 5 [illegible] R -2 [illegible] 10-
5 [illegible] -2 R [illegible] (365 [illegible]) [illegible].
B: [illegible].
C: [illegible] 0.05 [illegible] A [illegible] General
"identification tests [illegible] (121 [illegible] 1 [illegible]).

[illegible] **Heavy metals**: [illegible] 1.0 [illegible]
[illegible] "Limit test for heavy metals [illegible] 1 [illegible] (127 [illegible])
[illegible] A (128 [illegible] 1 [illegible]) [illegible] 20 [illegible].

[illegible] **Clarity and colour of solution**: [illegible] 2.0 [illegible] 10 [illegible]
[illegible] Yw2 [illegible] Colour
"of liquids [illegible] (53 [illegible] 1 [illegible]).

[illegible] **Sulfated ash**: [illegible] 1.0 [illegible].

.ȟ/ȠŸȠ 50 ȸȝ ÆȱÀöä ÆÅÂÅ ɍ Ü◦ȳ 105 ǥøäÀǵ ǦDZǿǻ ÆȺȝ ȤÀƶ :**Loss on drying** ȤȺÀDZǪöÀæ ÆȱÀöä

.3.3-2.7 ÛȱȠ/ȠŸȠ 25 ȯȤŸȚ ǒÀȽÀæ :**pH Value** ǒÀȽÀǤöä Ǥȶȩ

R1 ɄDZŸǯöä ȰǪȩèɉä Ȑþ ȯȤŸȚ ȸȠ ȰȠ 30 Ž ÛǦȩȓȤǤȒȠ ǦȹȿàȤȠ Ûȟ 0.25 ǦäàÀȩ āäǾÅ :**Assay** ǦÊÅÀȰʈä

ȤȽ Àȶȭ VS (ȯ/ȯȤȠ 0.1) ȰÅøȤŸȭǨǤöä Ȑþ ȝȠ ÀÅÀȞÅȿ ÛTS ȰǪȩèɉä Ȑþ/ȰȩȰǤəÂöä ǧÀǪȩèǕ ȸȠ ȰȠ 10 ȣÀȒÅ

.(142 ǦɄÀÔöä Û1 ÆŸŎä) A ǦŐÅÀÛöä Û"Non-aqueous titration ɄəÀȠŸöä Ȕèȥöä Ž ǥÀÅÀȞʈä" ȷäȤȺȝ ǨƠ ȣȤȍȤȠ

.$C_{12}H_{17}ClN_4OS,HCl$ ȸȠ ȠŸȠ 16.86 ȕȤÀȮÅ VS (ȯ/ȯȤȠ 0.1) ȰÅøȤŸȭǨǤöä Ȑþ ȸȠ ȰȠ 1 Ȱȭ

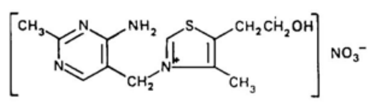
THIAMINI MONONITRAS

Thiamine mononitrate ǄǐǄǰǶǏǨǁǫ ǀǫǷȽǉ ǎȸǢǾǥ

$C_{12}H_{17}N_5O_4S$: **Molecular formula** ǦȩÅÀÂƨä ǦȣȩÔöä

327.4 :**Relative molecular mass** ǦȩǤÊÀöä ǦȩÅÀÂƨä ǦŸǪȮöä

:**Graphic formula** ǦȩȹÀȩǤʈä ǦȣȩÔöä



:**Chemical name** :ɄəÀȩȶȩȮöä ǖèɍä

Thiamine nitrate (salt); 3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methylthiazolium nitrate (salt); CAS Reg. No. 532-43-4.

.ǥÂȩɯȿ ǦÀȩÀǹ ǦɄəäÀöä ÛȐȩæǕ ɃøȤŸæ ȧȤɄÊȠ ȿǕ ÛǦȹȤŸȠ Ǩȡ ǧäøȤŸæ :**Description** ȤȍȤöä

Ǩȡ ȨȩŸȶȝ ÛTS (ȯ/ȟ750~) ȯȤȹÀǯÅɋä Ž ȨǼDZ ȷÀæȿǾöä ǴȩɄɁ ÜöÀʈä Ž ȷÀæȿǾöä ǴȩɄɁ :**Solubility** ȷÀæȿǾöä

.R ȷȤǪȩèɉä Ž āäȿǽ

.B ǩȠÀǪȩÀöä ȷȤȮȠ :**Category** ȤȺÀÔǪöä

ȸȠ ȶȶȝ ȷǕȿ ÛǦȩȹÆȞȠ Ǩȡ ÛŸÀÒǵǖæ ǦŎŸȣȠ ǦÅȿÀǵ Ž ǩȠÀȩǯöä ǧäÀǪȹ ɃǻÀǵǕ Ṣ̀Àǵ Ǣƶ :**Storage** ȸÅÂǺǪöä

.ǒȤȒöä

ÛÆüÀöä ȤDZŸȭ ȼȓÀȞǪæ ȨƶǿÆǨ ǩȠÀȩǯöä ǧäÀǪȹ ȭǿÆǪÅ :**Additional information** ǦȩȤÀȓǕ ǧÀȠȤŸȞȠ

.ǦȩÀȞöä ǥøäÀȈä ǧÀDZǻÀ Ž ȶÀèǕ ȰȮÀǪöä ȷȤȮÀȿ ÛǒȤȒöä āÀȩȡ Ž ȶøǪǵ

REQUIREMENTS ǨǤȠǗƱǨǨdž!ƒ

ǼĿÂĿ ɍş %98.0 ȸ Ǒǚ ɍ Ȁ ʔǮ ƙȠǼǮ ğǟǞ Ƀǻǵ Ƀǭ Ʒ :**General requirement** ǿǠǿ ǼǮÛǫţ

.ǦÂÂǑ ǥǻţ Ƃ ţǭǅǞǎǼ ǦǽÊȚ Û$C_{12}H_{17}N_5O_4S$ ȡ %101.0ȸ

Identity test ƕǏǊǈǁ ɭ ɛþǤƗƗ

ǼǪǼè ɃƘ ȡ Ǒ 0.5ş TS (ȯ/ȟ80~) ǿǭǻÔǟ ǼÊõşǿǼȽ ȡ Ǒ 1 ȣȒ ÛǒǙţ Ž ŋ 10 ǟǾ :A

10-5 ǥǼ ǞǑÊǼ õǞş R ȯǭǪǨ-2 ȡ Ǒ 5 Ʒ ǯǞ .ǼǥǞ ǞǞò ȯǭƚ ʔǑ ÜTS (ȯ/ȟ 10) ǿǭèǨǦǟ

.ȧǿǟ ǼǑǚ (Ǟ ǭǪǪ 365) ǦǅÊǞǦǟ ȧǭ Ǧǐ ɉ ǒǭȑ ş ƷùÊǟ ǿǼǞ ǒǭȑ Ž R ȯǭǪǨ-2 ǦǑǦù ɃǼǦǨ ÜĘǝǻ

.ǥƘȶ ʅ ǦɄǝǟǞ ǦǼǦ ÛǥÂǼư ǦǼǞǹ ǦɄǝǟǞ ɉǭǑǨ ÛǦƷÊǟ ǯǅǟ ʔǮ ȧǭɄÊţ ȡ ǦǮǮę ǦƚŧÕ ǞÎǞ :B

A ǑƷǞǟ ɄÛǠǞ ÜTS (ȯ/ȟ 15) ǟşǼǼΣǟ ğǞǮè ȡ Ǒ 2 ȣȒ Ǒ/ŋ 0.05 ȯǭȚ ȡ Ǒ 2 Ƃ :C

Û1 ǼǮǑǟ) ğǟǞǮ ǼƚƚÕ "General identification tests ǦȠǟ ȣǟǞèɍǟ ğǟǿǞȠǟ" ɉǟǭƷ ǨƠ ȣǭòǭţ

.(122 ǦɄÔǟ

ǿǞȠɍǟ" ɉǟǭƷ ǨƠ ȣǭòǭ ǭȽ ǞƚÕ ȟ 1.0 ǑƚǞÊǞ ǿǞȠɍǟ ȯǭȚ ƘȒɄǏ :**Heavy metals** ǦǮǑǯǟ ɉǻţ

ɉǻţ ʡǭȚ ȡǼ Ü(127 ǦɄÔǟ Û1 ǼǮǑǟ) 1 ǒǟǅqǟ "Limit test for heavy metals ǦǮǑǯǟ ɉǻţ Ǒǅɉ ɃǼΣǟ

.ȟ/ǿǞȡşǞǑ 20 ǼĿÂĿ ɍ Ü(128 ǦɄÔ Û1 ǼǮǑǟ) A ǦǑǞÛǮ ǼǦǨ ǦǮǑǯǟ ɉǻţ ȡ

ÈǼş ǼǞò ǒţ ȡ Ǒ 10 Ž ȟ 0.2 ȯǭȚ ɉǭǑ :**Clarity and colour of solution** ȯǭƚ ɉǭş ǒǞÔǟ

Colour ǑǝǭÊǟ ɉǭǑ" ɉǟǭƷ ǨƠ ȣǭòǭ ǭȽ Ȁ Ʒ ɉǿǑ ȀǼƷ Yw2 ɃǿǞţ ɉǭǟ ȯǭȚ ȡ ǞǯǑ ǥǼÎǞ ɉǭŋ

.(53 ǦɄÔǟ Û1ǼǮǑǟ) "of liquids

.ȟ/ŋ 1.0 ȸ ǼĿÂĿ ɍ :**Sulfated ash** ǨǞǮÊţ ǻȠǞǟ

.ȟ/ŋ 10 ȸ ǼǑǞǟ ǼĿÂĿ ɍ Ü°ǿ 105 ǥǿǟǥ ǦǅǿǻǼƷ Ʒƶ :**Loss on drying** ƷǼǅǫǞǞ ǼǑǞǟ

.7.5-6.0 ÛǑ/ŋ 20 ȯǭȚ ǒȽǞ :**pH Value** ǒȽǦǟ Ǧƚę

ÛR1 ɄǅǮǯǟ ǑǫèɉǏ Ȓþ ȯǭȚ ȡ Ǒ 30 Ž ÛǦȑǭǦȒŋ Ǧşǟǭ Ûȟ 0.1 Ǧǟę ǟǾ :**Assay** ǦÊǞǑţ

ǞƚÕ VS (ȯ/ȯǭ 0.1) ǑǞǿǭǮõǨǟ Ȓþ Ʒ ǞǞǟş ÛTS ǑǫèɉǏ Ȓþ/ƙǞÂǿǞ ȯǭǯǪ-1 ȡ Ǒ 0.15 ȣȒ

.(142 ǦɄÔǟ Û1ǼǮǑǟ) A ǦǑǞÛǟ Û"Non-aqueous titration ɄǝȠǮǟ Ûèǭǟ Ž ǥǞǞţ" ɉǟǭƷ ǨƠ ȣǭòǭ ǭȽ

.$C_{12}H_{17}N_5O_4S$ ȡ ŋ 16.37 ÙǭǑ VS (ȯ/ȯǭ 0.1) ǑǞǿǭǮõǨǟ Ȓþ ȡ Ǒ 1 Ǒõ

øøøøø

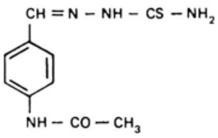
THIOACETAZONUM

Thioacetzone [illegible]

.$C_{10}H_{12}N_4OS$: **Molecular formula** [illegible]

236.3 :**Relative molecular mass** [illegible]

:**Graphic formula** [illegible]



:**Chemical name** [illegible]

4′-Formylacetanilide 4′-(thiosemicarbazone); *N*-[4-[[(amino-thioxomethyl)hydrazono]methyl]phenyl]acetamide; CAS Reg. No. 104-06-3.

[illegible] :**Description** [illegible]

[illegible] R [illegible] TS ([illegible]750~) [illegible] :**Solubility** [illegible]
10 [illegible] R.

[illegible] :**Category** [illegible]

[illegible] :**Storage** [illegible]

REQUIREMENTS [illegible]

%102.0 [illegible] %98.0 [illegible] :**General requirement** [illegible]
$C_{10}H_{12}N_4OS$ [illegible].

Identity test [illegible]

[illegible] :A
[illegible] .(42 [illegible] 1 [illegible]) "Spectrophotometry in the infrared region
[illegible] RS [illegible].

[illegible] dehydrated [illegible] 3.0 [illegible] :B
[illegible] 328 [illegible] 350 [illegible] 230 [illegible]
0.58 [illegible] 1 [illegible].

[illegible] 0.25 [illegible] VS ([illegible] 5) [illegible] 1 [illegible] 10 [illegible] :C
[illegible] TS ([illegible] 80) [illegible].

10 :D

(119 "General identification tests

1.0 :**Heavy metals**

(127 3 "Limit test for heavy metals

10 (128 A

2.0 :**Sulfated ash**

5.0 105 :**Loss on drying**

:**Related substances**

R4 (84 "Thin layer chromatography

R 9 10 R

(*P*-acetamidobenzalazine) 4.0 (B) 0.2 (A)

RS

(365 TS (130~

B A

2 :**Thiosemicarbazide**

50

25

VS (0.1) ceric

TS(100~) 250

0.8 TS (*o*-phenanthroline)

(1.0 VS (0.1) ceric

60 R 60 1.0 :**Assay**

60 60 TS 20

R

105

1 460.6 $C_{10}H_{12}N_4OS$

ØØØØØ

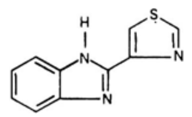
TIABENDAZOLUM

Tiabendazole üǸǰɌƐơǳǴƑĭŦǁƐ

.$C_{10}H_7N_3S$:**Molecular formula** ǦƐǺǺÂƨǻ Ǧ8ƐÔǿǻ

201.3 :**Relative molecular mass** ǦƐǦÊǺǿǻ ǦƐǺǺÂƨǻ ǦŸǪÒǿǻ

:**Graphic formula** ǦƐǫǺƐǦƫǻ Ǧ8ƐÔǿǻ



:**Chemical name** :ɄəǺƐȶƐÒǿǻ ȴèɍǻ

2-(4-Thiazolyl)benzimidazole; 2-(4-thiazolyl)-1*H*-benzimidazole; CAS Reg. No. 148-79-8.

.ǺǦǺÀǾǩ ǦΗɘǻÀǿǻ ƇǼʒ ȿǚ ǦΗɘǻÀǿǻ ƇǼʒ ÜǺǦǺÀǾǩ ȐƐǽǚ ȿǚ ȐƐǽǚ ȧȥΗÊɳ :**Description** Ȥòȥǿǻ

ǴƐΗì ǕTS (ȯ/ȟ750~) ȯȥǫǺǯǺɋǻ ȡɳ ǒÂDZ 150 Ž ǟǻȿǽ ǕǒǺƫǻ Ž ǟǻȿǽ Ƙȡ ǺƐŸȶʒ :**Solubility** ȷǺǽȿØǿǻ

.R Ƙǭɉǻȿ R ȳøȥȥȿøȥŸÒǿǻ Ž ȷǺǽȿØǿǻ

.ȷǻǼǺǼǿǻ ǻ̊øǺù :**Category** ȤƐǺÔǪǿǻ

.ȳǺȮǵǖǽ ǦǾŸ8ɳ ǦǺȿǺǵ Ž ȯȿàǻǼǺǽǺƐǪǿǻ ȘǺǵ Ǽƶ :**Storage** ȡǺÂÅǪǿǻ

REQUIREMENTS ƘǦǜǏƱƙdž!ƒ

%101.0ȡʒ ǼǺÂǺ ɍȿ %98.0 ȡʒ ǾǺ ɍ Ǻɳ ʔŸʒ ȯȿàǻǼǺǽǺƐǪǿǻ Ƀȥǫʒ :**General requirement** ȳǺȞǿǻ ǼŸÛǪƫǻ

.ǦǺǺǾǻ ǥǻ̊ǺƫǻƂǚ ƫȥDZÀǿǺǽ ǦǽȥÊƮ Û$C_{10}H_7N_3S$ ȡɳ

:**Identity tests** ȹǏǸǰǇǁƐ ǀƐþƑǴƗǮƐ

• ǺɳǙ ȷǚ ƐǦÛǺ ǹǻɍǹǺǦǪǹǻ A øǺǦǪǹɍǻ ȿǚ B ,C ȿ ,Dȿ.

ǿǻǺȶΣǻ ǨƠ ǦȞìɉǻ ǦǾÛǺɳ Ž ɄəȥȒǿǻ ȤƐÛǿǻ ǻ̂Ǻƈ" ȷǻȥǺʒ ǨƠ 8ȥòȥɳ ȥȽ Ǻȶõ øǺǦǪǹɍǻ ƐǦÛǺ :A

ǿǻǺȶΣǻ ǨƠ ǦȞìɉǻ îǺÔǪɳǻ ȤƐù ƐǽǺÛǪǺ .(43 ǦΗǺÔǿǻ Û1 ǼŸǑǿǻ) "Spectrophotometry in the infrared region

.ȯȿàǻǼǺǽǺƐǪŸǿ ɄȞDZÀƫǻ ȤƐÛǿǻ ʒɳ ȿǚ RS ȯȿàǻǼǺǽǺƐǪǿǻ ȡɳ ȼƐŸʒ ǾÔΗǪÊƫǻ ȤƐÛǿǻ ʒɳ

[illegible] VS [illegible] 0.1) [illegible] 4.0 [illegible] :B [illegible] 302 [illegible] 234 [illegible] 350 [illegible] 230 [illegible] 0.49 [illegible] 0.23 [illegible] 1 [illegible]

[illegible]-4 [illegible] 1 [illegible] 3 [illegible] VS [illegible] 0.1) [illegible] 5 [illegible] 5 [illegible] :C [illegible] R [illegible] 0.1 [illegible] R [illegible] TS [illegible] 45) [illegible] 10 [illegible] 2 [illegible]

[illegible] 1.0 [illegible] **:Sulfated ash** [illegible]

[illegible] 5.0 [illegible] 105 [illegible] **:Loss on drying** [illegible]

[illegible] **:Related substances** [illegible] 50 [illegible] R4 [illegible] (43 [illegible] 1 [illegible]) "Thin layer chromatography [illegible] 2 R [illegible] 8 R [illegible] 20 R [illegible] 10 (A) [illegible] :R [illegible] 10 [illegible] 0.15 (B) [illegible] 254) [illegible] B [illegible] A [illegible]

[illegible] R1 [illegible] 30 [illegible] 0.16 [illegible] **:Assay** [illegible] Non- [illegible] VS [illegible] 0.1) [illegible] VS [illegible] 0.1) [illegible] 1 [illegible] (142 [illegible] 1 [illegible]) A [illegible] "aqueous titration $C_{10}H_7N_3S$ [illegible] 20.13 [illegible]

ØØØØØ

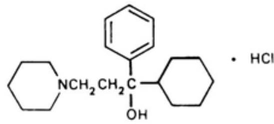
TRIHEXYPHENIDYLI HYDROCHLORIDUM

Trihexyphenidyl hydrochloride [illegible]

$C_{20}H_{31}NO,HCl$: **Molecular formula** [illegible]

337.9 **Relative molecular mass**: [illegible]

:**Graphic formula** [illegible]



:**Chemical name** :ƟǝǐƺƐƠǠǟ ƚèɍǟ

α-Cyclohexyl-α-phenyl-1-piperidinepropanol hydrochloride;
CAS Reg. No. 52-49-3.

.ǮƹǐşǻƹǛǑƐè ǕǒƹÊǑŁƕǠǟ ƺǖǿƹǛǒ̃şǿƺƐŁ :**Other names** ʔÀǹǕ ǒǟƧǕ

.ǠǛǟǑǩ ǦƕǝǟÀǟ ƇƎȝ şǕ ǦƕǝǟÀǟ ƇƎȝ ǕÀǠÔƞ ȐƐǣǕ şǕ ȐƐǣǕ ɃǿƹǛǣ ȧƹƕÊƞ :**Description** Ʒòƹǟ

.R ǒƹǬǛƫǟş R ǮǿƹƹşǿƹǛǑǟş TS (ǒ/ȟ750~) ǒƹǬǛǪǟ Ž ǡǟşǣ ǕǒǠƫǟ Ž ȷǟşǾǟ ǴƐƕì :**Solubility** ȷǟşǾǟ

.ǦƐƹÊƺǒ̃ǿǠǟ ǻǠȐƞ Üǧ ƺƐƺǒƹǑǟ ǻǠȐƞ ǒǟşǻ :**Category** ƷƐƺÔǪǟ

.ǮǠǑǵǜǣ Ǧǒ̃Ǜ8ƞ ǦǛşǠǵ Ž ǑƺƎƺƐƺÊǑƬƺǠǪǟ ƺǖǿƹǛǒ̃şǿƺƐŁ ȘǠǵ Ǽƶ :**Storage** ȸƺÂǺǪǟ

REQUIREMENTS ƘǦƕǟƱǩdž!ƒ

ɍş %98.0 ȸȝ ǑǒƺƐ ɍǠƞ ʔǛȝ ǑƺƎƺƐƺÊǑƬƺǠǪǟ ƺǖǿƹǛǒ̃şǿƺƐŁ Ƀƹǭƺ :**General requirement** ǮǠǨǟ ƎǛÛǪƫǟ
.ǦǠǠǑǟ ǥǻǠƫǟ ƂǕ ƫƹǅÀǟǣ ǦǣƹÊƮ Û$C_{20}H_{31}NO,HCl$ ȸƞ %101.0ȸȝ ƺƐƐ

:**Identity tests** ƕǏǋǊǁǁ ǀƐǷƑǶƣƐ

• ǕǠƞ ȷǕ A ǿǠǪǹɍǟ ŖǦÛƐ ȷǕ B ǧǟǿǠǪǹɍǟ ş CS ş DS.

A: ŖǦÛƐ ǿǠǪǹɍǟ ǠƫǒƹƤ ƹƐ ƺòƹƞ 8 ƘƠ ȷǟƹƺȝ ǡǠǣ" ƷƐÛǟ ƟǝƹȐǟ Ž Ǧǒ̃ÛǠƞ ǦǨìǰǟ ǒǟÀƫƩǟ ƘƠ ǒǟÀƫƩǟ "Spectrophotometry in the infrared region (ƺǛǑǟ Û1 ǦƕǠÔǟ 42). ƐÛǪǤǟ ŖǕù ƷƐǟ ǠÔǪƞ îǟ ƘƠ ǦǨìǰǟ ǒǟÀƫƩǟ ƞȝ ƷƐÛǟ ǒÔƕǪÊƫǟ ȝǛȝ ȸƞ ǑƺƎƺƐƺÊǑƬƺǠǪǟ RS şǕ ƞȝ ƷƐÛǟ ƫǅǦÀƫǟ ƟǅƹƺǖǿƹǛǒ̃şǿƺƐŁ ƺǖǿƹǛǒ̃şǿƺƐƮ .ǑƺƎƺƐƺÊǑƬƺǠǪǟ

B: ǡǟǾƐ 0.5 ƞǛƞ Ž 5 ǑƞǠ ȸƞ ǒƹǬǛƫǟ ǟƺǿǟ R ùƹǟ (0.1 ǒ/ǒƹƞ) ÛVS ǕǠȐǠş 8 ǦƐƫǒ̃ ǦƐƹǠǒ̃ ȸƞ ƺƐÊǒ̃şǿƺƐŁ ǦǣǠèǿ ǒǠȐƐǣ. ƟƫȝèǠǟ ÛǦǣǠèÀǟ ǯǠǟǿƹÔǟ (ǒ/ȟ80~) TS ǑǨƨ ƘǪǜǨ ǒƹǛǂǟ ƺƹǛǟ ʔǛȝ ǿǿş ǻǠǦȝ ÎǠǟ ȨƫÎǒ ÜR ƹƐÎǑǑ ǡǠèǠǡ ƬǟƹǨƶǠ ƘǪǜǨ ǦƐǬǠǬ ȸƞ ǑÀǣǡƮ ȸƞ ƘǪǜǨ Û8ǒ ǒǠƛ ǑÊ8ǩ ǑƠǕ ǑƐè ǕǠƫ ƺƐèǠ 0.6 ȸȝ ƺƐƐ ɍ) ȐǠǺǠƞ Ü8ȓ ƘƠ ƷǠƟş ÛR ǒƹǬǛƫǟ ȸƞ ǦƹǬǠǪ ǠǦǩ ǕǒǠƫǟ ȸƞ Ƙ8ǒ ǒǠƛ ǑÊ8ǩ ǡǠèǰ) ǠǛǟǑǩ ǯ 115 ǿǠƬÔǬɍǟ ǦǅǿǻǠǠǡ ÛǦȝǠè 2 ǥƺƞ R ÛǦǠǠǑǟ ÛǠǑǛƐÊǟ ǦƞƳŁ ȧƹƹ (ŖǦǝǟ ȸƞ ƚǛƞ 5 ǦǣǠǟǠǧ .(ǑƺƎƺƐƺÊǑƬƺǠǪǟ

C: ƟÛǨƐ 0.05 ǒ/ȟ ȸƞ ǒƹǛǂǟ ǑȝǠǠǪǟ B ƺòƹƫǟ 8 ƘƠ ȷǟƹƺȝ ǡǠǣ" ǧǟǿǠǪǹɍǟ ƕǠǨǣèɍǟ 8 ǠǨǟ ǦƞǠǨǟ General "identification tests ǑƐƐǒ̃ ǧǟƺǖǿƹǛǑǛǒ (ƺǛǑǟ Û1 ǦƕǠÔǟ 121).

.ȟ/ŋŸŋ 1.0 ȸȝ ÆȽÂȽ ғ :**Sulfated ash** ǨȦŸÊʈ ắȦŋȀöä

5.0 ȸȝ ÆŌÀöä ÆȽÂȽ ғ Ü°ÿ 105 ǥøäȀǵ ǦDZøÆæ ǨäȦǫ ɈàȘ ƂǗ ŌÔȄö ȤȦƺ :**Loss on drying** ȤȄȦDzǬöȦæ ÆŌÀöä
.ȟ/ŋŸŋ

ÜÆȽƎǬöä Ż ǦȦȥÆǬöä ȝŋ ɈȥæȀÒöä ÆȄÊõǗ ɄəȦǭ ȸŋ ƂȦʅä öȦʈä ȸŋ Ōŋ 100 Ž ȟ1.0 āäØȽ :**pH Value** öȦȽȦǦöä Ǧȶȇȩ
.6.0-5.0 ÛȯȥŸŧä äØȽ öȦȽȦæ

ȸŋ Ōŋ 1ȘöȦʈä ȸŋ Ōŋ 40 ȸŋ ǰȽÂŋ Ž ȟ 0.10 āäØȽ :**Piperidylpropiophenone** ɈȥȄȥȥȄäȘȀæ ŌȽÆȽƎȄæ
âȦŌȽ .Ōŋ 100 ȜȦǬɋ öȦʈä ȸŋ ǦȄȥȦõ Ǧȶõ ȣȦȒȽȘ ÛắƎȽ ÛƙǺÊǬöä ǥÆȝȦÊŋ VS (ȯ/ȯȥŋ 1) ȭȽøȥŸõȘøÆȄŦä Ȁþ
.0.5 ȸŋ ȀǯõǗ ɈȥȮȽ ғ ÛȀǬŋȥȹȦȹ 247 ǦDZȥŋ ȯȥȕ ÆȦȝ ȝŸȝɟä ȻÆǵ Ž ɭè 1 ȦȤȽǺǭ ǦŌǦȕ îȦȸ

ÛR1 ɄDzŸǰöä ȭȄǬȄèɟä Ȁþ ȯȥŸȚ ȸŋ Ōŋ 30 Ž ÛǦȄȑȥǦȒŋ ǦȹȘàȥŋ Ûȟ 0.5 ǦääȀȩ āäØȽ :**Assay** ǦÊȽȦŌʈä
ȥȽ Ȧȶõ VS (ȯ/ȯȥŋ 0.1) ȭȽøȥŸõƘǦöä Ȁþ ȝŋ ȀȽȦȞȽȘ TS ȭȄǬȄèɟä Ȁþ/ȭȄŌǦəÂöä ǧȦǬȄèǗ ȸŋ Ōŋ 10 ȣȦȒȽ
.(142 ǦɄȦÔöä Û1 ÆŸȮä) A ǦŌȽȀÛöä Û"Non-aqueous titration ɄəȦŋŸöä Ȁèȥöä Ž ǥȀȽȦȞʈä" ɈäȥȦȝ ǨƠ ȣȥȯȥŋ
.$C_{20}H_{31}NO,HCl$ ȸŋ ŋŸŋ 33.79 ȕȥȦȮȽVS (ȯ/ȯȥŋ 0.1) ȭȽøȥŸõƘǦöä Ȁþ ȸŋ Ōŋ 1 Ȭõ

ØØØØØ

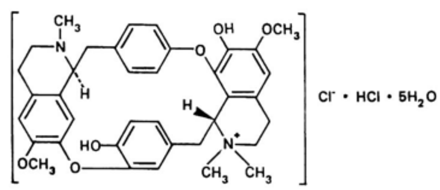
TUBOCURARINI CHLORIDUM

Tubocurarine Chloride DžĩþɛþNjǀNjǦNjǂǁǋ ǭĩþNjǂǀ

$C_{37}H_{41}ClN_2O_6,HCl,5H_2O$:**Molecular formula** ǦȄȦȽÂƨä ǦȣȄÔöä

771.7 :**Relative molecular mass** ǦȄǦÊȽöä ǦȄȦȽÂƨä ǦŸǬȮöä

:**Graphic formula** ǦȄȹȦȄǦʈä ǦȣȄÔöä



:**Chemical name** :ɄəȦȄȶȄȮöä ɭèғä

(+)-Tubocurarine chloride hydrochloride, pentahydrate; 7′,12′-dihydroxy-6,6′-dimethoxy-2,2′,2′-trimethyltubocuraranium chloride hydrochloride pentahydrate; CAS Reg. No. 6989-98-6 (pentahydrate).

.ǦɄəäȀöä ȻÆȝ ÜȀȦÔŋ ȀȄäǗ ȘǗ ȀȄäǗ ɃøȥŸæ ȧȥɄÊŋ :**Description** Ȥȯȥöä

ÄÆŸŧ3 ā ǟşǽ Ƙɗ ÜTS (ȯ/ȟ750~) ȯζφǰǰϥǟ ȸɳ ǟȍÂDZ 30 Žş ŏȦţǟ ȸɳ ǟȍÂDZ 20 Ž ā ǟşǽ :**Solubility** ȷȦǽşǾǟ
.R Ƙǫɉǟş R ŷǿζζşǿζŸȮǟş R ȷζǪȅɉǟ Ž

.ğŸȒȞǟ ȾǹȦɳ :**Category** ƵƎȂǪǟ

.ŷȦȮǵǘǽ ǴŎŸȣɳ ǴȦşȦǵ Ž ȸǟǿǟǿζǬζǽζǪǟ ǼǟǿζŸǬ ȘȦǵ Ǣƶ :**Storage** ȸǟÂǺǪǟ

3ɳ ŷ 270 ǴǽǟȦȩ ǥǿǟȦǵ ǴDZǿǼǽ ȸǟǿǟǿζǬζǽζǪǟ ǼǟǿζŸǬ ā şǾǟ **Additional information**: ǴƎζȦȓǟ ğȦɳζŸȞɳ
.ǬȮȦǪǟ

REQUIREMENTS ƘǴƅǕƱǅǆ!ƒ

ȸ3 ǼǟȂǟ ɍş %98.0 ȸ3 ǬǬǟ ɍȦɳ ʔŸ3 ȸǟǿǟǿζǬζǽζǪǟ ǼǟǿζŸǬ Ƀζǫ3 :**General requirement** ŷȦȞǟ ƸŸÛǪţǟ
.ǴȦȦǾǟ ǥǻȦţǟ ƂǗ ţζDZȦȮȦǽ ǴǽζÊƮ Û$C_{37}H_{41}ClN_2O_6$,HCl ȸɳ %102.0

Identity test ȟȉǸǊǉǁ l ɛƥƑǴƗƣɛ

.ɃǟȦǬ Ȧƥǖ ȷζǟ ŏȖǴǽ ǰǪǟ ÜTS ǴȒȦǟ ğǟȦǪǷ ȸɳ Ǭɳ 1 ȣȦȒǟş ŏȦţǟ ȸɳ Ǭɳ 1 Ž ȠŸɳ 10 ā ǟǾǟ :A
ÛȦȒȠǖ ȷζǟ ǰǪǟ ÜTS (ȯ/ȟ 25) ǬǟƘȦǟ ǼǟǿζŸǬ ȸɳ Ǭɳ 0.1 ȣȦȒǟş ŏȦţǟ ȸɳ Ǭɳ 1 Ž ȠŸɳ 10 ā ǟǾǟ :B
.ȾǝȦɳ ŷȦƥ ʔŸ3 ǴȦζǼǪǟ Ǽǟ3 ǞƎǟǽ ǴǴȂǟ

General ǴɳȦȞǟ ȣǟȦȞǪȅɍǟ ğǟǿȦǴǪȠǟ" ȷǟζǟ3 ȞƠ ȣζȍζţǟ B Ǭ3ȦǟǪǟ Ǭɳ/Ƞɳ 20 ȯζŸƬ ȾÛȞǟ :C
.(121 ǴȞȦȂǟ Û1ǼŸǬǟ) ğǟǼǟǿζŸȮŸǟ ÂƎŧŧǬ "identification tests

Ûğȥ3ȅ 3 ǥǼɳ ȂǬǪÊƎǟ ǬȀ Ǭɳ/Ƞɳ 10 ȯζŸƬ ǬŧȞǪÊǟ :**Specific Optical rotation**: Ⱦ3ζǟǟ ɃȂǴǴǟ ȂǟşǼǪǟ
.$[a]_{D}^{20°C} = +210 \text{ to } +220°$ ÜǴȦȦǾǟ ǥǻȦţǟ ƂǗ ţζDZȦȮȦǽ ƸÊƷş

ȣȦȒǟ ÛŏȦţǟ ȸɳ Ǭɳ 150 Ž ȟ 0.25 ā ǟǾǟ :**Chloroform-soluble substances** ŷǿζζşǿζŸȮȦǽ ǴǽǟşǾǟ ǻǟζţǟ
ȸɳ Ǭɳ 20 ȦƬǟɳ ǬǬ ÛğȦƎŧǬ 3 ǿǽ ȮŸǺǪÊǟş ÛR ŷζǟǻζȂǟ ƘDZşǿƎȽ ğȦǫζǽȦȮȦ 3ǴÎɳ ȯζŸƬ ȸɳ Ǭɳ 5
Ûȧǿşǻ Ž ŷǿζζşǿζŸȮǟ ȯζŸƬ ǴȉȦǟ ÛŏȦţǟ ȸɳ Ǭɳ 10 ǿǽ ǴǴǬȦţǟ ŷǿζζşǿζŸȮǟ ğȦȍŸǹ ǬÊȣǨ .R ŷǿζζşǿζŸȮǟ
ȦǺǴǟ .ǴǵȦȉȦǟ ƂǗ ğɍζÊȣǟ ȣȦȒǨş ÛǬɳ 5 ȦƬǟɳ ǬǬ ÛR ŷǿζζşǿζŸȮǟ ȸɳ ƘǪȞǽȦǪɳ ƘǪƎŧȮǽ ǴȞȉȦţǟ ǬÊȣǨ
ǴǟŧǮǟ ȷǟş ǼǟȂǟ ɍ ÛǥǼǵǟş Ǵ3ȅ ǥǼɳ °ŷ 105 ǴDZǿǼǽ ǴǟŧǮǟ ƵȦΘş ÛȾǝȦɳ ŷȦƥ Ž ǴǵȦȉȦǟş ğɍζÊȣǟ ƸǬȦɳ
ǬǟǿζŸǬşǿƎȽǟ Ȓƥ ȸɳ Ǭɳ 1 ȣȦȒǟ Ż .ā şǾǨ ɍ ǴǟŧǮǟ ÜǴǟŧǮǟ ƂǗ ŏȦţǟ ȸɳ Ǭɳ 10 ȣȦȒǟ .(%2.0) Ƞɳ 5 ȸ3
.ǴǟŧǮǟ ā şǾǨ ÜTS (ȯ/ȟ70~)

.ȟ/Ƞɳ 2.5 ȸ3 ǼǟȂǟ ɍ :**Sulfated ash** ȞȦŸÊţǟ ǻȦɳȦǟ

ɶ) ȒǺǺȠ Ȕ8ȑ ǨƠ °ȳ 100 ǵøǟǵ ǦǱøǼǟ ǨǟǪ ȷǟȘ Бǚ ǬȎǬ ȤǺƺ :**Loss on drying** ȤǼǱǬǟǼ ǼȎǟǟ .ȟ/ȠȠ 120 ȸȝ ǼȎǟǟ ǼǺǺ ɶȘ ȟ/ȠȠ 90 ȸȝ ǼȎǟǟ ǬȎǺ ɶ Ȕ(ɄǬǟǟɭ ȴȠ 5 Șǚ ȯǺȮȅǟȤǼȭ 0.6 ǟȘǟǱǪǺ

.6.0-4.0 ȖǬȠ/ȠȠ 10 ȯȤȚ ǒǺȽǟ :**pH Value** ǒǺǺǦǟ ǦȽǼȩ

ȳǺȽɯ ȕȤǼǺ ȖR1 ɄǱȲǟ ǬǼǼȅɉǟ Ȓƥ ȸȠ ǬȠ 20 Ž ȖǦǼȑȤǦȒȠ ǦǫȘǟȤȠ Ȗȟ 0.5 ǦǟǟǺȩ ǟǟØǺ :**Assay** ǦȆǺǺǬȶǟ .TS ǬǼǼȅɉǟ Ȓƥ/ǬǼǬǦǟǟ ǧǺǼȅǚ ȣǺȒǺ ȸȠ ǬȠ 10Ș R ǬǼǼȅɉǟ ǼǺøǼǼǚ ȸȠ ǬȠ 60 ȣǺȒǺȘ Ȗǻɜǻ ȖɄǟǺȠ ȤȽ ǺȽȭ potentiometrically ǼȚƨǟ ǟǺǼǬȠ ǦǺǺȚǟǟ ǦȖǬǫ ȸǦȞ ȖVS (ȯ/ȯȤȠ 0.1) ǬǺøȤǱȭǨǦǟ ȒȽɯ ǺǺȞǺ .(142 ǦȞǺǬǟ Ȗ1 ǼȲǬǟ) A ǦǬǺǺȖǟ "Non-aqueous titration ɄǟǺȠȲǟ ȔȅȤǟ Ž ǵǺǺȞȶǟ" ȷǟȤǺȝ ǨƠ ȣȤȍȤȠ .$C_{37}H_{41}ClN_2O_6,HCl$ ȝȠ 34.08 ȕȤǺȮǺ VS (ȯ/ȯȤȠ 0.1) ǬǺøȤǱȭǨǦǟ Ȓƥ ȸȠ ǬȠ1 ǬȭØØØØØ

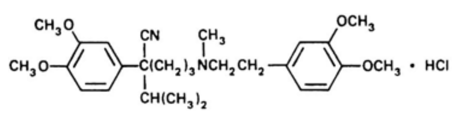
VERAPAMILI HYDROCHLORIDUM

Verapamil Hydrochloride ȕǏǱǰǦɛƥǏƻǁǦ ǫǏƥǋǂǀǋƥǫǏǉ

$C_{27}H_{38}N_2O_4,HCl$: **Molecular formula** ǦǼǺǺȂƨǟ Ǧ8ǼȎǟǟ

491.1 **Relative molecular mass**: ǦǼǦȆǺǟ ǦǼǺǺȂƨǟ ǦȲǫȮǟ

:**Graphic formula** ǦǼǫǺǼǦȶǟ Ǧ8ǼȎǟǟ



:**Chemical name** :ɄǟǺǼȽǼǬǟ ȴȅɶǟ

5-[(3,4-Dimethoxyphenethyl)methylamino]-2-(3,4-dimethoxyphenyl)-2-isopropylvaleronitrile hydrochloride; α-[3-[[2-(3,4-dimethoxyphenyl)-ethyl]methylamino]propyl]-3,4-dimethoxy-α-(1-methylethyl)benzeneacetonitrile monohydrochloride; CAS Reg. No. 152-11-4.

.ǼǦǺǺǬǨ ǦȞǟǟǺǟ ǅǼȝ Șǚ ǦȞǟǟǺǟ ǅǼȝ ȔǼǦǺǺǬǨ ȒǼǚ Șǚ ȒǼǚ ɃøȤǲ ǟȤȞȆȠ :**Description** ȤȍȤǟ

Ž ȷǟȘØǟǟ ǺǴ ȔTS (ȯ/ȟ750~) ȯȤǫǺȝǺɋǟ Ž ǼǲǼȩ ǟǟȘǽ ȔǒǺȶǟ ȸȠ ǼǒǺǱ 20 Ž ǟǟȘǽ :**Solubility** ȷǟȘØǟǟ .R ȳøȤȤȘøȤȲȮǟ

.ǦɯØǟǟ ǻǺȒȠ ǒǟȘǻ :**Category** ȤǼǺȎǪǟ

.ǒȤȒǟ ȸȠ ɁȽȝ ȷǚȘ ȖȳǺǬǵǟ ǦǬȲ8ȠǦǺȘǺǵ Ž ǬǼȠǟǟǨǺǟ ǼǺøȤȲȭȘøǼȽ ȘǺǵ Ƽƺ :**Storage** ȸǺǺǺǪǟ

ȸȝ ǼƛÂƛ ɍȿ %99.0 ȸȝ ȌȬƛ ɍǺŋ ɁŸȝ ȌǢŋǻǟǨǺȫ ǼƛøȥŸǪȿøǼǢŁ ɃȥǬȜ :**General requirement** ȳǺǨȫ ǼŸÛǬʈ
.ǤǺǺȫ gǻǺʈ ɃǕ ʈȥǅǺȫǺǣ ǤǣȥÊƬ Û$C_{27}H_{38}N_2O_4,HCl$ ȸŋ %101.0

Identity test ʜɪǸǋǋǀ ǀ ɛɓƑǴƢɛ

- .E، D، C، B ǧǟøǺǬǹɍǟ ȿǕ A øǺǬǹǟ ȨǤÛƛ ɹǕ ǺŋǕ

ǒǟǺɫƩǟ ǨƠ ǤǨȉɟǟ ǤȰÛǺŋ Ž ɄǝȥȒȫ ȤǢÛȫ âǺǢȩ" ɹǟȥǺȝ ǨƠ ȣȥȍȥŋ ȥŁ ǺɫȬ øǺǬǹɍǟ ȨǤÛƛ :A
ǒǟǺɫƩǟ ǨƠ ǤǨȉɟǟ îǺÔǬŋǟ ȤǢǜ ȨǣǺÛǬƛ .(43 ǤɄǺÔȫ Û1 ǼŸǑȫ) "Spectrophotometry in the infrared region
.ȌǢŋǻǟǨǺȫ ǼƛøȥŸȪȿøǼǢƬ ɄǨǅǺʈ ȤǢÛȫ ȝŋ ȿǕ RS ȌǢŋǻǟǨǺȫ ǼƛøȥŸȪȿøǼǢŁ ȸŋ ȼǢŸȝ ȌÔɄǬÊʈ ȤǢÛȫ ȝŋ
ÛVS (ȯ/ȯȥŋ 0.1) ȬƛøȥŸȪȿøǼǢƬǟ ȐƥŽ Ȍŋ/ȳǟǺȡȿǺȌŋ 20 ÂǢȬǺǩ ɃǣȯȥŸƬ îǺÔǬŋǟ ȤǢǜ ɃǼǤƛ :BĈ
ǺǬŋȥȹǺȹ 278، 229 ǤǅȥʈǕ ɃȥǜǼƛȝ ƙǢɫƬȝǕ ȸƛǼǥ ÛǺǬŋȥȹǺȹ 350، ǺǬŋȥȹǺȹ 230 ƙǣ ǤǅȥŋȯǟȥǜǕ Ž ǼŁǺÎƛ ǺŋǼƛȝ
.ɃǟȥǬȫ ɁŸȝ Û0.24، 0.63 ȸƛøŁ ǤǅȥʈǟɃȥǜǼƛȝ ɭè 1 ǤȹǺǺǩǣ ǤȰǤǜ îǺǬŋŸǤƛ ǛǢǤƛǺȬǩ

ȸŋ Ȍŋ 0.2، TS (ȯ/ȟ 570~) ȬƛøȥǺŸÊȫ ȐƥŽ ȸŋ Ȍŋ 0.5 ȣǺȒƛ ÛȯǺʈ ȸŋ Ȍŋ 2.5 Ž ŋŸŋ 20 āǟøƛ :C
.ǢǼǅ ǼǥǺɟ ǺǺȍǕ ȯȥŸƬ ɟǬǬȫ ǤȝǺÊǣ āȿøǩ ÛǤǢǅÊǺǺǣ ǤǺèø ɟǬǺǩ ÛTS (ȯ/ȟ 10) ȳȥǢèǺǩȥǤȫ ǧǺǺȣǺŋƙǣ
eneral identification ǤŋǺǨȫ ȣǟǺǨǬèɍǟ ǧǟøǺǬǹǟ" ɹǟȥǺȝ ǨƠ ȣȥȍȥʈ BȌȝǺǺǬȫ Ȍŋ/ŋŋ 20 ȯȥŸƬ ɄÛǨƛ :D
.(121 ǤɄǺÔȫ Û1ǼŸǑȫ) ǧǟǼƛøȥŸȮȫ ÂǢɫɫȬ "tests
- .°ȳ 143 ǤǣǟǺȩ øǺȽÔȹɍǟ ǥøǟǺǥ ǤǅøǻE :E

ȸŋ ɃǺƪǟ ǒǺʈǟ ȸŋ Ȍŋ 10 Ž ȟ 0.50 ȯȥŸƬ ɹȥȮƛ :**Clarity and colour of solution** ȯȥŸɫǟ ɹȥȯ ȿ ǒǺǺȍ
.ɹȥŸȫ ƇǼȝȿ ǢǢȥǺȍ ɹȥǣǺȮȫ ǼǢÊȬǕ ɄǝǺǺȩ

ȐƥŽ ȸŋ Ȍŋ 5 Ž ȟ 0.10 āǟøƛ :**Readily carbonizable substances** ǤȫȥȾÊǣ ǤǺǣǺȮŸȫ ǤŸǣǺȰȫ ǻǟȥʈǟ
ɹȥŸȫ ȯȥŸƬ ȸŋ ǥǼɟ ǺǯȬǕ ȼȹȥŸǩ ɹȥȮƛ ɍȿ ÛȨǝǺȩǻ 5 ǼǨǣ ǢǢȥǺȍ ȯȥŸɫǟ ǤǤÔƛ .TS (ȯ/ȟ1760~) ȬƛøȥǺŸÊȫ
.(53 ǤɄǺÔȫ Û1ǼŸǑȫ) Colour of liquids ȌǝǟȥÊȫ ɹȥȯ" ɹǟȥǺȝ ǨƠ ȣȥȍȥŋ ȥŁ ǺɫȬ ǺȽǬȹøǺȌŋ ǼƛȝYw2 ɃøǺǢǨʈǟ
ȟ/ŋŸŋ 1.0 ȸȝ ǼƛÂƛ ɍ :**sulfated ash** ǨŸǺÊɫʈǟ ǻǺŋǺȫ

5.0 ȸŋ ǺǯȬǕ ǼȬǺȫ ɹȥȮƛ ɍ ÛǤǺȥǺŋ 105 ǥøǟǺǥ ǤǅøǼǣ ǨǣǺȹ ɹǟȿ ɃǕ ȤǺƶ :**Loss on drying** ȤǢǺǅȥȬǺǣ ǼȬǺȫ
.ȟ/ŋŸŋ

.6.5-4.5 ÛR ɹȥǣǺȮȫ ǼǢÊȬǕ ɄǝǺǺȩ ȸŋ ɃǺƪǟ ǒǺʈǟ Ž ÛȌŋ/ȟ 0.05 ȯȥŸƬ ǒǺŁǺǣ ǤɫǢȩ :**pH Value** ǒǺŁǺǤȫ ǤɫǢȩ

Related substances

"Thin-layer chromatography

A: (84 ... 1) R5 ... R 15 ... R 85 ... 25 (B) ... 50 (A) ... B: R ... 10 ... 50 (C) ... 10 ... 5 ... 110 ... 15-10 ... TS (200) ... 50 ... R 2 ... R ... B ... A ... C. B.

B: 5 R ... 20 R ... 70 ... A ... A. R ... 5 R ... 10 R1 ... 30 ... 0.5 **Assay** TS ... 1-0.15 ... TS ... VS (0.1) ... VS (0.1) ... 1 ... (142 ... 1) A "Non-aqueous titration

$C_{27}H_{38}N_2O_4,HCl$ 49.11

Additional requierments for Verapamil hydrochloride for parenteral use

(56 ... 4) "Parenteral preparations

Bacterial endotoxins (30 ... 5) "Test for Bacterial endotoxins ... 16.7 RS ...

ØØØØØ

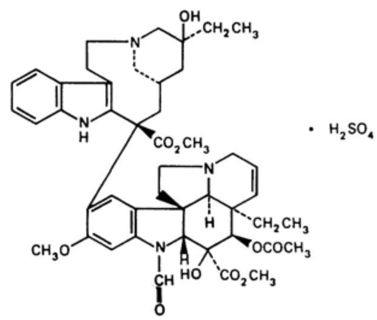
VINCRISTIN SULFAS

Vincristin sulfate ĎžĭĦƨĭƥǀǚƧǁɛ ǀƑƧǂƨ

.$C_{46}H_{56}N_4O_{10},H_2SO_4$:**Molecular formula** ĞĔǺǺƨā Ğ8ĔÔöā

923.0 **Relative molecular mass**: ĞĔĞÊǺöā ĞĔǺǺƨā ĞŶǪÒöā

:**Graphic formula** ĞĔɸǺĔĞƫā Ğ8ĔÔöā



:**Chemical name** :ȔəǺĔƪĔÒöā ǈèɼā

Leurocristine sulfate (1 : 1) (salt); 22-oxovincaleukoblastine sulfate (1 : 1) (salt); CAS Reg. No. 2068-78-2.

.ĞĦɘāǺöā ƇǼȝ ǕĦŸĔŸę ǺǺÔŋ БǕ ȐĔǽǕ ȸǿɀŸǽ ɼ şǕ ȸǿɀŸǽ ȧɀĦÊŋ :**Description** Ɀòɀöā

.R ƘǪɉā ǺĔŸɫȝ āāşǽ Ƙȡ ǕTS (ȯ/ȟ750~) òɀɸǺǯǺqā Ž ȷǺǽşǾöā ǴĔĦì ǕöǺƫā Ž ȷǺǽşǾöā Ǻǵ :**Solubility** ȷǺǽşǾöā

.ǺǺŸǺŸö ȳǺè öāşǻ :**Category** ⱫĔǺÔǪöā

ĞĎǱǿǼǽ ȷÂơ ȷǕş ǕöɀȒöā ȸŋ ĞĔɫƮ ǕȳǺÒǵǖǽ ĞŐŸ8ŋ ǴǺşǺǵ Ž ƘǪÊǺǺÒǺǺöā ğǺǺŸè ȘǺǵ Ǽƶ :**Storage** ȸǺÂǺǪöā

.°ȳ 10ş 2 Ƙǽ ǥǿāǺǵ

.ĞĔƫÊöā ǥǼǺǼìş ĞǴüǺǪÊŋ ƘǪÊǺǺÒǺǺöā ğǺǺŸè :**Additional information** ĞĔɀǺȓǕ ğǺŋɀŸĦŋ

ȧǺÎǺǪèāş ǼŸƨā ȝŋ ¢èǺǪ ǼǺΘş ǕɃǼǺɉǺǽ ƘǪÊǺǺÒǺǺöā ğǺǺŸè ǴŸŋǺĦŋ ɁǼö ǿǾΣāş ǴǕĔΣā ǽǺơā Ǽƶ :ǺǺǾƠ

.öāɀƬǺǽ ĞöɀŌǺƫā ğāǿǾöā

REQUIREMENTS ƘǴǚǁƱƘǆǃ!ƒ

ȸȝ ǼǺÂǺ ɼş %95.0 ȸȝ ŌǾǺ ɼǺŋ ʔŸȝ ƘǪÊǺǺÒǺǺöā ğǺǺŸè ȸɀǪƠ :**General requirement** ȳǺȞöā ǼŸǕǪƫā

.ĞǺǺǾöā ǥǻǺƫā БǕ ƫɀǄǺöǺǽ ĞāɀÊƮ Ǖ$C_{46}H_{56}N_4O_{10},H_2SO_4$ ȸŋ %105.0

:**Identity test** ƕǏǋǊǁɛ ǀɛƥƑǴǯɛ

.DȘ CȘ B ğäøȦǬǹ ɽä şǗ DȘ A øȦǬǹä ĘǤÛȂ ɉǗ ȦɳǗ ●

ŏäȀȽΣä ǨƠ ǦȞ ȉ ǰä ǦŐÛȂɳ Ž ɄəɀȒöä ȤȨÛöä âȦɇȩ" ɉäɀȂɜ ǨƠ ȣɀòɀɳ ɀȽ Ȧȴõ øȦǬǹ ɽä ĘǤÛȂ :A ŏäȀȽΣä ǨƠ ǦȞ ȉ ǰä î ȦÔǬɳä ȤȨÛ ĘæȦÛǬȂ .(43 ǦɄȦÔöä Û1 ǼǛÖä) "Spectrophotometry in the infrared region ğȦȂǛè ȡɳ ȻȨǛɜ ŌÔɄǬÊȶä ȤȨÛöä ɜɳ °ǯ 40 ǥøäȀǵ ǦǲȤøǼæ Ǧɜ Ȧè 16 ǥǼɳ ȐȦȂǺȂɳ Ȕ8ȓ ǨƠ ǦȂȦÔä ǥǻȦȴǛö .ƙǬÊȂȀȮȂȂöä ğȦȂǛÊö ɄǶǲȤȀȶä ȤȨÛöä ɜɳ şǗ ŎǬȦɯ ɀǗ ɁǛɜ ǥȀȒɬä RS ƙǬÊȂȀȮȂȂöä

ǦÊȨəȀöä ǦȞŐǤöä ĘæȦÛǬǩ "**Related substances** ǦŏȦÎȶä åäɀȶä" ɉäɀȂɜ ǨƠ ȦŐǥɽ ȣɀòɀȶä øȦǬǹ ɽä ȀȚȹä :B .C ȯɀǛɬȦæ ȦȾȨǛɜ ŌÔɄǬÊȶä ȪǛǩ ɜɳ ǥǼÎöäş ȀȾȚȶäş ɜȩɀȶä Ž A ȯɀǛɬȦæ ȦȾȨǛɜ ŌÔɄǬÊȶä

ɈǬȂȂ ǗǥǼǵäş ǦŐȨȩå ǦææȦȩ ȀŎǬÊȨö ŏȦǬȂş TS ȪȂøɀǛõşøǼȨȚä Ȑƥ/ƙǛȨȹȦȂöä ȡɳ Ōɳ 0.2 ǦææȦȩ ȣȦȒȂ ɳǛɳ 1 ƃǗ :C .(ƙǬèȲǤȀȨȂöä ğȦȂǛè ȡɜ ȂȨɯ) ƃȦŐǨȀæ ɉɀö

General ǦɳȦȞöä ȣäȀȞǬè ɽä ğäøȦǬǹä" ɉäɀȂɜ ǨƠ ȣɀòɀȶä B ŌɜȦȂǬöä Ōɳ/ɳǛɳ 20 ȯɀǛȚ ɄÛȞȂ :D .(123 ǦɄȦÔöä Û1ǼǛÖä) ğȦȂǛÊǛö ȂȨȽȽõ "identification tests

ɀǛȨõ 0.6 ȡɜ ǼȂÂȂ ɽ) ȐȦȂǺȂɳ Ȕ8ȓ ǨƠ °ǯ 40 ǥøäȀǵ ǦǲȤøǼæ ȤȦȥ :**Loss on drying** ȤȨȂǲǬöȦæ ǼŐȦöä .ȟ/ɳǛɳ 120 ȡɳ ȀǯõǗ ǼŐȦöä ɉɀȮȂ ɽ ǗǦɜ Ȧè 16 ǥǼɳ (ɄŐǤəä ȴǛɳ 5 ǦææȦȩ şǗ ȯȦÖèȦæ

.4.5-3.5 ǗŌɳ/ȟ 1.0 ȯɀǛȚ ŏȦȽȦǤöä :**pH Value** ŏȦȽȦǤöä ǦȽȨȩ

ǦŐȨȩȀöä ǦŐǤÛöä ãäȀÎǬèä" ɉäɀȂɜ ǨƠ ȣɀòɀɳ ɀȽ Ȧȴõ øȦǬǹ ɽä ĘǤÛȂ :**Related substances** ǦŏȦÎȶä åäɀȶä 40 ȡɳ ɈȂȂɳş ǦǛ8ɳ ǥǻȦȴõ R2 ȦÒȨǛȨÊöä ǦɳǛȽ ǯǼǺǬÊǩ Û(84 ǦɄȦÔöä Û1 ǼǛÖä) "Thin-layer chromatography ĘǤÛȂ .õȀɄǬɳ øɀÛõ R ƙɳǛȨȜȂɋä ɄəȦȂǬ ȡɳ ǯɀǲǵ 3ş R ǯøɀɀşøɀǛÒöä ȡɳ ȦȽǲǵ 20ş R ȡȂɀɀɀÛöä ȡɳ ȦȽǲǵ ȀǬö ɄǛȨȶä Ž øȦǬǹ ɽä ǥǻȦɳ ȡɳ ɳǛɳ 10 (A) Ƀɀȝ :R ȯɀȹȀȨȶä Ž ŌȨöȦȚ 3 ȡɳ ǯäȀȡşȦÒɳ 5 ǦɄȨȦÔöä ɁǛɜ ǛÔȦȂɳ ȶÂȹ ǼȞæ .ȀǬö ɄǛȨȶä Ž RS ƙǬÊȂȀȮȂȂöä ğȦȂǛè ȡɳ ɳǛɳ 10 (C)ş ȀǬö ɄǛȨȶä Ž øȦǬǹ ɽä ǥǻȦɳ ȡɳ ɳǛɳ 0.20 (B)ş ǦȨǲÊȂȦǤöä ȧɀɀ ǦȞ ȉ ǰä ŏɀȒæ ãäȀÎǬèɽä ȔÛɯ ȌɄȦȂş ÛŏäɀȚä Ž ȤǲɀǬö õȀǬǩ Û ãäȀÎǬèɽä ǥȀǲǵ ȡɳ ǦɄȨȦÔöä ŌÔɄǬÊȶä ɜŐǤöä ȡɳ ǥǼ ȉ ȀǯõǗ ɉɀȮǨ ɽ ǗǦÊȨəȀöä ǦȞŐǤöä ŏȦȂǯèȦæ ÛA ȯɀǛɬȦæ ȦȾȨǛɜ ŌÔɄǬÊȂ ǦȞæ ǦȂǗ .(ȀǬɳɀȹȦȹ 254) .B ȯɀǛɬȦæ ȦȾȨǛɜ

ãȦŐȂ .Ōɳ 500 ȝȦǬȹɋ R ȯɀȹȦȜȨȶä ȡɳ ǦȨɀȦõ ǦȨȽõ Ž ÛǦȨȓɀǤȒɳ Ǧȹşàɀɳ ÛɳǛɳ 10 ǦææȦȩ ãäȂȂ :**Assay** ǦÊȂȦŐȶä $C_{46}H_{56}N_4O_{10}$, ʔɀǬȚ ǼÊȜş ȀǬɳɀȹȦȹ 297 ǦǲȤɳ ȯɀȗ Ǽȝɜ ȴè 1 ǦȹȦǺȜä ǦŐǤÛö ɄȽȚɜǰä ȻǼǵ Ž ȯɀǛɬäȂȽ î ȦǬȂ ÛH₂SO₄ ǯäǼǺǬèȦæ ǦȽȨȩ ǦȨòȦȶä ȀȓȦȶä absorptivity value 177 .($A_{1cm}^{1\%} = 17.7$)

ØØØØØ

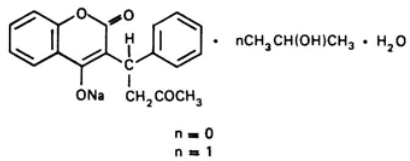
WARFARINUM NATRICUM

Warfarin sodium !ǸĵǏǭǸĵƬǁ ǅǐƥƺƥƐǸĵ

$C_{19}H_{15}NaO_4$; $C_{19}H_{15}NaO_4,C_3H_8O,H_2O$ (Hyclate) :**Molecular formula** ǦƐǺƛƧǟ Ǧ8ƐǑǿǟ

330.3; 408.4 (Hyclate) :**Relative molecular mass** ǦƐǤȆƛǿǟ ǦƐǺƛƧǟ ǦŸǪǑǿǟ

:**Graphic formula** ǦƐǫǺƐǤţǟ Ǧ8ƐǑǿǟ



:**Chemical name** :ɄəǺƐɫƐǑǿǟ ǋèɾǟ

3-(α-Acetonylbenzyl)-4-hydroxycoumarin sodium salt; 4-hydroxy-3-(3-oxo-1-phenylbutyl)-2*H*-1-benzopyran-2-one sodium salt; CAS Reg. No. 129-06-6.
3-(α-Acetonylbenzyl)-4-hydroxycoumarin sodium salt compound with 2-propanol monohydrate; 4-hydroxy-3-(3-oxo-1-phenylbutyl)-2*H*-benzopyran-2-one sodium salt 2-propanol monohydrate.

.ǦɄəǟǺǿǟ ƇƐȝ ǛɃǿƺŸǽ ɍ ȿǛ ɃǿƺŸǽ ȐƐǛ ȧƺɄȆƞ :**Description** Ƶòƺǿǟ

Ž ɉǺǽȿǾǿǟ ǴƐɄì ǛƬS (ȯ/ȟ750~) ȯƺǫǺǯǪƣǟ Žȿ ǒǺţǟ ȸƞ Ǽǵǟȿ ǒǺǅƵ ȸƞ ǬȿǛ Ž ǟǟȿǽ :**Solubility** ɉǺǽȿǾǿǟ
.R ƘǪɉǟȿ R ȳǿƺƺȿǿƺŸǑǿǟ

.ǞǯǺǪǿǟ ȝǫǺƞ ǒǟȿǻ :**Category** ƵƐǺǑǪǿǟ

.ǒƺȒǿǟ ȸƞ ɁɫƷ ɉǛȿ ǛŷǺǑǵǽǟ ǦǬŸ8ƞ ǦǺȿǺǵ Ž ȳƺǺǻƺǑǿǟ ȸǺǿǺƺǿǟȿ Ș ǺǵƐƶ :**Storage** ȸǺƛǺǪǿǟ

ǛǦǺǿƺŸǽ ɍ ȿǛ ǦǺǿƺŸǽ ǵǻǺţǟ ƘǫǺõ ǟǽǛ Ǻƞ ȳƺǺǻƺǑǿǟ ȸǺǿǺƺǿǟȿ ǦǺȿǺǵ ɁŸƷ ȸƐǦɫ ɉǛ Ɛƶ :**Labelling** ǋƐèƺǪǿǟ
.clathrate form ȭƐƖŢǟ ȬǑìȿ

ô ǞȞǪǿǺǽ ȭǿƐǪǨ .ǒƺȒǿǺǽ ɉƺŸǿǟ ǦǿƐǪƞ ǵǻǺƞ ȳƺǺǻƺǑǿǟ ȸǺǿǺƺǿǟȿ **Additional information**: ǦƐƺǺȓǟ ǧǺƞƺŸȞƞ
.ɁŸƷɉǟ ǵǿǟƩǟ ǧǺǅǿǻ Ž ţǞèǛ ȭǑǺǪǿǟ ɉƺǑǺȿ ǛǒƺȒǿǟ ǟƐȡ Ž ɁǿǪǵ ǛƐƶǿƐǨ ƺƧǟ ǦǽƺùǞǻ

REQUIREMENTS ƘǦǻǏƱȥǆ!ƒ

ȸƷ ƐǺƛǺ ɾȿ %98.0 ȸƷ ȬȭǺ ɾǺƞ ɁŸƷ ȳƺǺǻƺǑǿǟ ȸǺǿǺƺǿǟȿ ɃƺǪƷ :**General requirement** ȳǺȞǿǟ ƐŸǛǪţǟ
.ȯƺǫǺǽǞǽ-2 ȸƞ ǦƐǺǃǟȿ ǦƐəǺƞŸǿǟ ǵǻǺţǟ ɃǛ ţƺǅǞǿǺǽ ǦǽƺȆƮ Ǜ$C_{19}H_{15}NaO_4$ ȸƞ %102.0

TS (70~) 1 25 0.1 :A
105 (C
.(B .(162

:B A
.(43 1) "Spectrophotometry in the infrared region
. RS
:C A B
.(123 1) "General identification tests

TS (1000~) 5 10 1 :D
clathrate 5 VS (0.0167) 2
.

10 0.50 :**Clarity and colour of solution**
.TS2 R

Determination of water .**Water**
45 0.4 (145 1) "by the Karl Fischer method
.

.8.3-7.2 R 10 :**pH Value**

: **Related substances**
5 R4 (84 1) "Thin-layer chromatography
R 2 R 5 R
20 (A) :R 20
0.020 (B)
254)
.B A

10 1.25 :**Absorbance in alkaline solution**
15 TS (50)

[illegible] 385 [illegible] 1 [illegible] 0.3 [illegible] (50)

[illegible] 25.0 [illegible] 25.0 [illegible] 0.8 [illegible] -2 [illegible] 10 [illegible] swirling [illegible] (0.125) [illegible] 30 [illegible] 40 [illegible] 250 [illegible] 20 [illegible] 60 [illegible] .75° [illegible] 250 [illegible] (80~) [illegible] 5 [illegible] 30 [illegible] (0.1) [illegible] 20.0 [illegible] well [illegible] well [illegible] (420~) [illegible] 3 [illegible] (0.1) [illegible] -2 [illegible] 1.001 [illegible] (1.0) [illegible] 1 [illegible] -2 [illegible] 83 43 [illegible] 3 [illegible]

0.01) [illegible] 0.1 [illegible] **Assay** [illegible] (0.01) [illegible] 1000 [illegible] 10 [illegible] 100 [illegible] $C_{19}H_{15}NaO_4$ [illegible] 308 [illegible] 1 [illegible] RS [illegible] RS [illegible] $C_{19}H_{15}NaO_4$ [illegible] 1.071 [illegible] 0.03±0.47 [illegible]

ØØØØØ

ZINCI OXYDUM

Zinc oxide [illegible]

ZnO : **Molecular formula** [illegible]

81.38 :**Relative molecular mass** [illegible]

:**Chemical name** [illegible]

Zinc oxide; CAS Reg. No. 1314-13-2.

[illegible] :**Description** [illegible]

ÕŀǿʐŸõşǿǼŦTǟ ȐȾШ ǡǟşǣ ÜTS (ȯ/ȟ750~) ȯʐǾǰƣǟş ǒǻʈǟǣ ǞŸȾʒ ǡǟşǣ Ƙɖ :**Solubility** ɹǟşØǒǟ
.TS (ȯ/ȟ70~)

.ǟǟʐõ ǞȞȑ ʐɳ ŌȾȞĘŀ ȯǼȞɳ ȐǣǨ :**Category** ƸƎÂÔǒǟ

.ǞǼƎDZ ǦŌŸ8ɳ ǦşǸǵ Ž ÕǷÂǒǟ ǼƎÊõǕ ȘǸǵ ǼƵ :**Storage** ȸÂÅǒǟ

.ǒǟʐTǟ ȸɳ ɹʐǟÀÒǒǟ ǼƎÊõǕ ɄǟǺǫ ǞƵǿǼǩ ÕǷÂǒǟ ǼƎÊõǕ ÒǪƺ :**Additional information** ǦƵʐǺȑǟ ǧǺɳʐŸȞɳ

REQUIREMENTS ƘǦǸǬƱǩǳ!ƒ

%100.5 ȸʒ ǼŀÂŀ ɍş %99.0 ȸʒ ŌŌŀ ɍǺɳ ɁŸʒ ÕǷÂǒǟ ǼƎÊõǕ Ƀʐǫʒ :**General requirement** ȳǺȞǒǟ ǼŸÛǪʈǟ
.ǞDZǟǺù (ǦŸǞÎʈǟ) ǥǼɳǺʈǟ ǥǺʈǟ ƁǕ ʈʐDZÀǒǻǣ ǦǣʐÊƬ ÛZnO ȸɳ

:**Identity test** ɦǏNjNJǁ lɛƥƑƓƢɛ

.ǼǮǪǒǻǣ ÀÀȍɉǟ ɹʐŸǒǟ ȯşÂŀ ɹǕ ȏ ÀǪǺŀ ÜǥǺʈǟ ȸɳ ŌƎŸǫ ǿǟǼŌɳ ǥǼÎǣ ȸÅÊŀ :A
ǼƎǷǺƎȅşƘʐ ȸɳ Ōɳ 0.15 ȣǺȒŀ ÛTS (ȯ/ȟ 70~) ÕŀǿʐŸõşǿǼŦTǟ Ȑƿ ȸɳ Ōɳ 2.0 Ž ƞŸɳ 20 ǡǟØŀ :B
.ǥǺȒƯ ǒǺȒƎǣ ǦǣǺȅǿ ŌÒÎǪǩ ÜTS (ȯ/ȟ 45) ȳʐƎȅǺǩʐǦǒǟ

Ǻȶõ ʒǣǺǪş ÛTS (ȯ/ȟ 70~) ÕŀǿʐŸõşǿǼŦTǟ Ȑƿ ȸɳ Ōɳ 35 Ž ȟ 1.6 ȸɳ ȯʐŸƬ ŌȾȞĘŀ .**Arsenic** ǸƎǷǿÂǒǟ
ɍ Ü(130 ǦȞǺÔǒǟ Û1 ǼŸǑǟ) ."Limit test for arsenic ǸƎǷǿÂǒǟ ŌDZɉ ɃǼΣǟ ǿǺǪȵɍǟ" ɹǟʐǺʒ ǨƠ ȣʐȍʐɳ ʐȽ
.ȟ/ȳǟȀɖşȀÒɳ 6 ȸɳ ȀǰõǕ ǸƎǷǿÂǒǟ ȸɳ ʔʐǪɉǟ ɹʐÒŀ

10 ʒɳ 2.0 ǯÂƺ :**Carbonates and acid-insoluble substances** ȐȾΣǺǣ ǦǣşØǒǟ Ƙɖ ǻǟʐʈǟş ǧǺǫʐǣȀÒǒǟ
ɍ ÛǺȾǪÊʈǟ ÕǺȞǪǒǟ ʒɳ ɄǺɳ ȳǺƿ Ž ȸǺÊǩş ÛTS (ȯ/ȟ100~) ÕŀʐǺŸÊǒǟ Ȑƿ ȸɳ Ōɳ 30 ȣǺȒŀ ÛǒǺʈǟ ȸɳ Ōɳ
.ɹʐŸǒǟ ƇǼʒş ȣǺȍ ǰǩǺǒǟ ȯʐŸɉǟş ɹǟǿʐʐ ǫǼʒ

ȯʐŸɉǟ ŌɳǺȞŀ .ǒǺʈǟ ȸɳ Ōɳ 30ş TS (ȯ/ȟ250~) ÕŀǿʐŸõşǿǼŦTǟ Ȑƿ Ōɳ 5 Ž ȟ 0.20 ǡǟØŀ .**Iron** ǼŀǼΣǟ
ǼŀÂŀ ɍ .(129 ǦȞǺÔǒǟ Û1 ǼŸǑǟ) "Limit test for iron ǼŀǼΣǟ ŌDZɉ ɃǼΣǟ ǿǺǪȵɍǟ" ɹǟʐǺʒ ǨƠ ȣʐȍʐɳ ʐȽ Ǻȶõ
.ȳǟȀɖ/ȳǟȀɖşȀÒɳ 200 ȸʒ

ÛR ɄDZʐǯǒǟ ÕƎǪƎȅɉǟ Ȑƿ ȸɳ Ōɳ 5 ȣǺȒŀ ÛǞǼƎDZ õǺʒ ÛǒǺʈǟ ȸɳ Ōɳ 20 ƁǕ ȟ 2 ȣǺȒŀ .**Lead** ΐǺȍÀǒǟ
ǰǪǺŀ ɍ ÜTS (ȯ/ȟ 100) ȳʐƎȅǺǩʐǦǒǟ ǧǺɳşÀõ ȸɳ Ōɳ 0.25 ȣǺȒŀ Ż .ȯʐŸɉǟ ÀǪǜǪŀ ɁǿǪǵ ɄǺɳ ȳǺƿ ɁŸʒ ǜʐǼȴş
.ǦǺȅǿ şǕ ÀÒʒ

ǼŌÀǒǟ ɹʐÒŀ ɍ ÛǷ 500 ǥǿǟǵ ǦDZǿǼǣ ǨǺǫ ɹǟş ƁǕ ȟ1.0 (ŌǞÎŀ) ǼɳÀŀ .**Loss on ignition** ǼƎɳÀǪǒǻǣ ǼŌÀǒǟ

.ȟ/ηŸŋ10 ȸŋ Ȁǯȭǖ

TS ȯɀɸǺǯǺɋǟ /ƙǺǻǺǯɀ ȯɀǼȦȫǟ ȸŋ Ȫŋ 0.1 ȣǺȒǺ ǛȸǹǺȆǟ ȫǺƫǟ ȸŋ Ȫŋ 10 Ž ȟ1 ǯǺƹ .**Alkalinity** ǴǺɀŸȪǟ
ʔøǪǵ VS (ȯ/ȯɀŋ 0.1) ȭǺøɀŸȭşøǼȬǟ Ȑ þ ȸŋ Ȫŋ 0.3 ȸŋ Ȁǯȭǖ ǼŸǛǪǺ ɍ ȫǟȀ þ ǴǵǺȉȀȫǟ ǨɸǺȭ ǟǽǖ ǗǴȉȀş
.ɉɀŸȫǟ ȯşȂǺ

TS (ȯ/ȟ 120~) ȭǼǪȅɉǟ Ȑ þ ȸŋ Ȫŋ 10 Ž ǛǴǼȑɀǴȒη ǴɸşȁɀŋǛȟ 0.15 ǴǟǟȀę ǡǟǾǺ :**Assay** ǴȆǺȪƫǟ
ǴȞȦȎǟ Ǜ1 ǼŸȎǟ) "Complexometric titrations ǧǟǼȪȞƫǟ ȃǺǼȪη ǧǟȀǺȞƫǟ" ɉǟɀǺȝ ǨƠ ȣɀȍɀŋ ɀȽ Ǻȶȭ ȀǺȞǺş
.ZnO ȸŋ ŋŸŋ 4.069 ȕɀǺȮǨ VS (ȯ/ȯɀŋ 0.05) ǰɀǺǻɀȎǟ ɄǝǺǺǫ ǧǺǪǺǼǖ ȸŋ ȀǪǟ ɄŸǼŋ Ȫȭ .(135

LIST OF REAGENTS, TEST SOLUTIONS,
AND VOLUMETRIC SOLUTIONS

[illegible]

LIST OF REAGENTS, TEST SOLUTIONS, AND VOLUMETRIC SOLUTIONS

[illegible]

Acacia R. [illegible] *Acacia sengal* (L.) [illegible]

Description [illegible] 1 [illegible] 3 [illegible]

Solubility [illegible] TS (~750 [illegible]) [illegible] R.

Ash. [illegible] 50 [illegible]

Acid-insoluble ash [illegible] 5.0 [illegible]

Insoluble matter [illegible] 5 [illegible] 100 [illegible] 10 [illegible] TS (~70 [illegible]) [illegible] 15 [illegible] 105 [illegible] 5 [illegible]

Tannin [illegible] 10 [illegible] 1 [illegible] 10 [illegible] 0.1 [illegible] TS (25 [illegible]) [illegible]

Acacia [illegible] **TS** (5 [illegible]) [illegible] 5 [illegible] R [illegible]

p-[illegible] **RS (*p*-Acetamidobenzalazine)** [illegible]

[illegible] **(Acetate buffer)** [illegible] **4.5 TS**:

Procedure [illegible] 10.9 [illegible] 100 [illegible] 8 [illegible] R [illegible] 1000 [illegible]

:**TS** Û**4.7** ŏÀŁÀæ Û**(Acetate buffer)** ğÀQĒèɟă Ǧǝăǿắ

Ȑþ ȸ Ōȵ 3.35 ȣÀȒȿ ÛŏÀʈă ȸ Ōȵ 100 Ž R ȳɀȿắɀÔöă ğÀQĒèÛ ȸ ȟ 8.4 āăǾȿ :*procedure ǒăÄDZɋă*

.ŏÀʈÀæ Ōȵ 1000 БÛ ƵÀƩʂ ÛǮÂɀ ÛɄDzŸǯöă ŌĒQĒèɟă

:**TS** Û**5.0** ŏÀŁÀæ Û**(Acetate buffer)** ğÀQĒèɟă Ǧǝăǿắ

Ȑþ ȸ Ōȵ 6 ȣÀȒȿ ÛŏÀʈă ȸ Ōȵ 100 Ž R ȳɀȿắɀÔöă ğÀQĒèÛ ȸ ȟ 13.6 āăǾȿ :*procedure ǒăÄDZɋă*

.ŏÀʈÀæ Ōȵ 1000 БÛ ƵÀƩ ÛǮÂɀ ÛɄDzŸǯöă ŌĒQĒèɟă

:**TS** Û**5.5** ŏÀŁÀæ Û**(Acetate buffer)** ğÀQĒèɟă Ǧǝăǿắ

Û°ȳ 35 ǦDZǿÆöă БÛ ȸÅÊȿ ÛŏÀʈă ȸ Ōȵ 50 Ž R ȳɀȿắɀÔöă ğÀQĒèÛ ȸ ȟ 54.4 āăǾȿ :*procedure ǒăÄDZɋă*

.ŏÀʈÀæ Ōȵ 1000 БÛ ƵÀƩʂ ʓÀł .R ɄDzŸǯöă ŌĒQĒèɟă Ȑþ ȸ Ōȵ 10 ŏÙǦæ ȣÀȒȿ ÆȿƎQöă ÆȞæ .ɡǿʂÀȒöă Æȿʒ

ȸ ɁɀQȚ БÛ ŏÀʈÀæ ƵÀƩ ÛTS (ȯ/ȟ300~) ŌĒQĒèɟă Ȑþ :**TS (ȯ/ȟ120~) Acetic acid** ŌĒQĒèɟă Ȑþ

.d~1.016 Ü(ǦȿÀŌǩ ȯ/ȯɀȵ 2) ÀQŸöă Ž ȟ120 ȠŸǦȿ $C_2H_4O_2$

ȸ ɁɀQȚ БÛ ŏÀʈÀæ ƵÀƩ ÛTS (ȯ/ȟ300~) ŌĒQĒèɟă Ȑþ :**TS (ȯ/ȟ90~) Acetic acid** ŌĒQĒèɟă Ȑþ

.(ǦȿÀŌǩ ȯ/ȯɀȵ 1.5) ÀQŸöă Ž ȟ 90 ȠŸǦȿ $C_2H_4O_2$

ȸ ɁɀQȚ БÛ ŏÀʈÀæ ƵÀƩ ÛTS (ȯ/ȟ300~) ŌĒQĒèɟă Ȑþ :**TS (ȯ/ȟ5.0) Acetic acid** ŌĒQĒèɟă Ȑþ

.d~1.0007 ÜÀQŸöă Ž ȟ 5.0 ȠŸǦȿ $C_2H_4O_2$

ǦĒöʂắ ǦĒǝÀĒȶĒŐ ǦĒȞDZÀȵ ɡắȵ :**RS (Amiloride hydrochloride)** ÆȿǿɀŸĒȵɟă ÆȿǿɀŸŐʂǿÆĒŁ

ÜȷʂÛ-5-ƙȯʂăăƘæ-3-ŌĒÆɀ-1-ŌĒǮĒȵ ɄǝÀÀQ-3Û2-ɀÆĒȵÛ-4 .$C_{11}H_{13}NO_3$:**R (4-Aminoantipyrine)** ȸȿƘæ ɄǿQQÛ ɀÆĒȵÛ**-4**

.aminopyrazolone ȷɀȯʂăăƘæɀÆĒȵÛ Üampyrone ȷʂƘǦȵÛ

.ȧɀȞÊȵ ʂÛ ǦǦǵÀì ŏăÀÀȍ ğăǿɀŸæ :*Description Ƶȍɀă*

Ž ǞÆDZ ȷÀæʂǾöă ǴĒȞì ÜTS (ȯ/ȟ750~) ȯɀɸÀǯȿɋă Ž ȷÀæʂǾöă Àǵ ÜŏÀʈă Ž ȷÀæʂǾöă ŌĒŸę :*Solubility ǦĒɸÀæʂǾöă*

.R ƘQɟă

.ǦȿÀŌǩ °ȳ 108 :*Melting temperature ǿÀȚÔɸɍă ǦDZǿắ*

:**TS1 (4- Aminoantipyrine)** ȸȿƘæ ɄǿQQÛ ɀÆĒȵÛ**-4**

Ōȵ 0.25 ɁŸʒ ɃɀQƷ ȯɀɸÀǮĒʈă ȸ Ōȵ 25 Ž R ȸȿƘæ ɄǿQQÛ ɀÆĒȵÛ-4 ȸ ȟ0.125 āăǾȿ :*Procedure ǒăÄDZɋă*

.TS (ȯ/ȟ420~) ŌȿǿɀŸŐʂǿÆĒTă Ȑþ

:TS2 (4-Aminoantipyrine) ꝺǺƘǽ ɄøǬǭǗ ɀǼɳǕ-4

Ŏɳ 10 ꝺɳ ǰǺȂɳ ȣǺȒǺȘ ŏǺţǟ ꝺɳ Ŏɳ 30 Ž R ꝺǺƘǽ ɄøǬǭǗ ɀǼɳǕ 4 ꝺɳ ȟ0.1 ǦǟǟǺȩ ǡǟǾǺ :*Procedure ŏǟǞǮǭǟ*

ǦǼɀǺȭ ǦǼȶȮǽ ƵǺƩ ǕVS ($\dot{o}/\dot{o}$ɀɳ 1) ȳɀǺǻɀȎǟǟ ǼǼȆȭȘǿǼǼ ꝺɳ Ŏɳ 2Ș TS ($\dot{o}/$ȟ200) ȳɀǺǻɀȎǟǟ ğǺǭɀǽǺȭ ꝺɳ

.Ŏɳ 100 ǯǺǬǭɋ ŏǺţǟ ꝺɳ

.ǺǮǟǺǕ ꝺǺƘǽ ɄøǬǭǗ ɀǼɳǕ-4 ǺȒƷ ȷǕ Ǣȥ :*ǴŢǵȲɳ*

.$C_3H_3N_3O_2S$:**R (2-Amino-5-nitrothiazole)** ȯȘǟǺǼǬȘǺǬǼǭ-5-ɀǼɳǕ-2

.ƃǺȭǩǺǽ ǺǺȍǕ ƃǕ ǺȒƯ ǺǺȍǕ fluffy Ƶǹɵ ȧɀɄȆɳ :*Description Ƶȍɀǟ*

Ž ȷǺǟȘǾǟǟ ǴǼɄȉ ǕǦǺǺǺţǟ ǦǼǭǼȟţǟ ȏɀȶΣǟ Ž ǡǟȘǽ ǕǒǺţǟ Ž ǺǼǮ ȷǺǟȘǾǟǟ ǴǼɄȉ :*Solubility ǴǼǭǺǟȘǾǟǟ*

.R ȳǿɀɀȘǿɀǗȮǟǟ Ž ǺǼǗȶȝ ǡǟȘǽ ғ ǕR ƘǭɉǟȘ TS ($\dot{o}/$ȟ750~) ȯɀǭǺǯǺɋǟ

.ȬȮǺǬǟǟ ȝɳ °ȳ 198 :*Melting temperature ǿǺȚȎǭғǟ ǦǮǿǻ*

.C_6H_7NO :**R (4-Aminophenol)** ȯɀǼɀɀǼɳǕ-4

.ǺǦǺǺȭǩ ȐǼǽǕ ȘǕ ȐǼǽǕ ɃǿɀǗǽ ȧɀɄȆɳ :*Description Ƶȍɀǟ*

.ȬȮǺǬǟǟ ȝɳ ǺǦǺǺȭǩ °ȳ 184 :*Melting temperature ǿǺȚȎǭғǟ ǦǮǿǻ*

ǺǬǗǟǟ Ž ȟ 50 ŋǗǦǺ NH_3 ꝺɳ ȜɀǬȚ ƃǕ ŏǺţǺǽ TS ($\dot{o}/$ȟ260~) ǺǼǭɀɳɉǟ ƵǺơ :TS ($\dot{o}/$ȟ50~) **Ammonia** ǺǼǭɀɳɉǟ

.d~0.977 Ǖ(ǺǦǺǺȭǩ $\dot{o}/\dot{o}$ɀɳ 3)

:**TS2 (Ammonia buffer)** ǺǼǭɀɳɉǟ Ǧəǿǟǻ

ƵǺƩȘ TS ($\dot{o}/$ȟ260~) ǺǼǭɀɳɉǟ ꝺɳ Ŏɳ 650 Ž R ȳɀǼǭɀɳɉǟ ǼǺǿɀǗȭ ꝺɳ ȟ 67.5 ǡǟǾǺ :*Procedure ŏǟǞǮǭǟ*

.Ŏɳ 1000 ǰǬǺǺ ʔøǬǵ ŏǺţǺǽ

ꝺɳ ȟ 100 ʔǗȝ ɃɀǬƷ R ȳɀǼǺɳɉǟ ğǺǬǼȅɉ ȯɀǗȚ :**TS ($\dot{o}/$ȟ100) Ammonium acetate** ȳɀǼǭɀɳɉǟ ğǺǬǼȅǕ

.ǺǬǗǟǟ Ž $C_2H_7NO_2$

ꝺɳ ȟ 38.5 ʔǗȝ ɃɀǬƷ R ȳɀǼǭɀɳɉǟ ğǺǬǼȅǕ ꝺɳ ȯɀǗȚ :**TS ($\dot{o}/$ȟ40) Ammonium acetate** ȳɀǼǭɀɳɉǟ ğǺǬǼȅǕ

.(ǺǦǺǺȭǩ ǺǬǗǟǟ/ ȯɀɳ 0.5) ǺǦǺǺȭǩ ǺǬǗǟǟ Ž $C_2H_7NO_2$

.ǺǮǟǺǕ TS ($\dot{o}/$ȟ40) ȳɀǼǭɀɳɉǟ ğǺǬǼȅǕ ƘȒơ Ǣȥ :*Note ǴŢǵȲɳ*

ꝺɳ ȟ 2 ʔǗȝ ɃɀǬƷ R ȳɀǼǭɀɳɉǟ ğǺǬǼȅǕ ꝺɳ ȯɀǗȚ :**TS ($\dot{o}/$ȟ2) Ammonium acetate** ȳɀǼǭɀɳɉǟ ğǺǬǼȅǕ

.ǺǦǺǺȭǩ ǺǬǗǟǟ Ž $C_2H_7NO_2$

.ǺǮǟǺǕ TS ($\dot{o}/$ȟ2) ȳɀǼǭɀɳɉǟ ğǺǬǼȅǕ ƘȒơ Ǣȥ :*Note ǴŢǵȲɳ*

:TS Û4.62 ǒǺȽǺǽ (**Ammonium acetate buffer**) ÿƶĿƣƶƞɉǟ ğǺǪȄèǓ Ǧəǿǟǻ

ÕȄǪèɉǟ Ȓƥ ȯǺȶǰȁèǺǽ 4.62 БǓ TS (ȯ/ȟ100) ÿƶĿƣƶƞɉǟ ğǺǪȄèǓ ǒǺȽǺǽ ǴĦƲÔł :*Procedure ǒǟǞǅǫǟ*
.TS (ȯ/ȟ60~)

:TS (**Ammonium mercurithiocyanate**) ÿƶĿƣƶƞɉǟ ĘǦəà ğǺǫǺȄèƶĿǬ

ȡƞ ǦĿƶǺõ ǦĿȶõ Ž R ÕȄÕǦəÂǒǟ ǼǺǿƶŸõ ȡƞ ȟ 27ȿ R ÿƶĿƣƶƞɉǟ ğǺǫǺȄèƶĿǬ ȡƞ ȟ 30 ǟǟǾǺ :*procedure ǒǟǞǅǫǟ*
.Ōƞ 1000 ʓǺǪǫɋ ǒǺƫǟ

:TS (**Ammonium molybdate/sulfuric acid**) ÕǺǿƶǺŸÊǒǟ Ȓƥ/ÿƶĿƣƶƞɉǟ ğǟǼǦĿǒƶƞ

ÕǺǿƶǺŸÊǒǟ Ȓƥ ȡƞ ǦĿƶǺõ ǦĿȶõ Ž R ÿƶĿƣƶƞɉǟ ğǟǼǦĿǒƶƞ ȡƞ ȟ 0.5 ǟǟǾǺ :*Procedure ǒǟǞǅǫǟ*
.Ōƞ 10 ʓǺǪǫɋ TS (ȯ/ȟ1760~)

:TS (**Ammonium molybdate/vanadate**) ğǟǻǺǫǺƶ/ÿƶĿƣƶƞɉǟ ğǟǼǦĿǒƶƞ

R ÿƶĿƣƶƞɉǟ ğǟǻǺǫǺƶ ȡƞ ȟ 0.1ȿ Ǧȶʒǟǒǟ ǦȩƶĦÊƫǟ R ÿƶĿƣƶƞɉǟ ğǟǼǦĿǒƶƞ ȡƞ ȟ 4 ʓǺǺ :*Procedure ǒǟǞǅǫǟ*
Ōƞ 100 БǓ ȤǺƸȿ TS (ȯ/ȟ1000~) ÕǺǞǪǺǒǟ Ȓƥ ȡƞ Ōƞ 20 ȣǺȒǺ .ǒǺƫǟ ȡƞ Ōƞ 70 Ž Ǧȶʒǟǒǟ ǦȩƶĦÊƫǟ
.ǒǺƫǺǽ

.(37 ǦĦǺÔǒǟ Û1963 ÛSRIP) $(NH_4)_2S_2O_8$:**R (Ammonium persulfate)** ÿƶĿƣƶƞɉǟ ğǺǺŸèǨǽ

:**TS (Ammonium persulfate/phosphate buffer)** ğǺǺèƶǺǒǟ Ǧəǿǟǻ/ÿƶĿƣƶƞɉǟ ğǺǺŸèǨǽ

ʓǺǪǫɋ TS Û7.4 ǒǺȽǺǽ ÛǦĿƶǺõ ğǺǺèƶƶ Ǧəǿǟǻ Ž R ÿƶĿƣƶƞɉǟ ğǺǺŸèǨǽ ȡƞ ȟ 10 ǟǟǾǺ :*Procedure ǒǟǞǅǫǟ*
.Ōƞ 100

.(39 ǦĦǺÔǒǟ Û1963 ÛSRIP) $NH_4[Cr(NH_3)_2(SCN)_4],H_2O$:**R (Ammonium reineckate)** ÿƶĿƣƶƞɉǟ ğǺÒȄǺǿ

ȡƞ ȟ 10 ʔŸʒ ȸƶǪʒ R ÿƶĿƣƶƞɉǟ ğǺÒȄǺǿ ȯƶŸƬ :**TS (ȯ/ȟ10) Ammonium reineckate** ÿƶĿƣƶƞɉǟ ğǺÒȄǺǿ
.ǺǪŸǒǟ Ž $NH_4[Cr(NH_3)_2(SCN)_4]$

ȡƞ ȟ 50 ʔŸʒ ȸƶǪʒ R ÿƶĿƣƶƞɉǟ ğǺƞǺǺŸè ȯƶŸƬ :**TS (ȯ/ȟ50) Ammonium sulfamate** ÿƶĿƣƶƞɉǟ ğǺƞǺǺŸè
.ǺǪŸǒǟ Ž $NH_4OSO_2NH_2$

:**TS Ammonium sulfide** ÿƶĿƣƶƞɉǟ ǼĿǺŸè

25 БǓ ȣǺȒǺ .TS (ȯ/ȟ100~) ǺĿƣƶƞɉǟ Ž R ƙǅȿǿǼĿƬǟ ǼĿǺŸè ȡƞ ʒǦÎƞ ȯƶŸƬ ǺȒʒ :*Procedure ǒǟǞǅǫǟ*
.TS (ȯ/ȟ100~) ǺĿƣƶƞɉǟ ȡƞ Ōƞ 50 ȯƶŸǂǟ ȡƞ Ōƞ

[illegible] **(II) :TS (Ammonium thiocyanate/cobalt(II)nitrate)**

Procedure [illegible]: 20 [illegible] 5 [illegible] R (II) [illegible] 100 [illegible]

[illegible] R [illegible].

[illegible] **R Ammonium vanadate:** NH_4VO_3.

Description [illegible]: [illegible].

Solubility [illegible]: [illegible] (~100 ml/L) TS.

[illegible] **RS (Amodiaquine hydrochloride):** [illegible].

[illegible] **RS (Amphotericin B):** [illegible] (Tetraenes

[illegible] **R (Anthrone):** $C_{14}H_{10}O$.

Description [illegible]: [illegible].

Solubility [illegible]: [illegible] (~750 ml/L) TS [illegible]
[illegible] (~100 ml/L) TS.

(Solubility in carbon tetrachloride R) [illegible]: R [illegible] 0.5 [illegible] 10 [illegible]
[illegible] R [illegible].

Melting range [illegible]: 154-156 °[illegible].

[illegible] **TS (Anthrone):**

Procedure [illegible]: 35 [illegible] R 100 [illegible] (~1760 ml/L) TS.

[illegible] **RS (Azathioprine):** [illegible].

[illegible] **RS (Bacitracin zinc):** [illegible].

[illegible] **RS (Beclometasone dipropionate):** [illegible].

[illegible] **R (Benzyl alcohol):** C_7H_8O.

Description [illegible]: [illegible].

Miscibility [illegible]: [illegible] 25 [illegible] (~750 ml/L) TS [illegible]
R [illegible] R.

Boiling temperature [illegible]: 204 °[illegible].

Mass density: ρ_{20} = 1.05

RS (Betamethasone valerate):

RS (Biperiden):

RS (Biperiden hydrochloride):

R (2-Butanol)-2: $C_4H_{10}O$ (SRIP 1963 53).

R (Butyl acetate): $C_6H_{12}O_2$.

Description:

Miscibility: TS (750~).

Mass density: ρ_{20} = 0.88

R (Butylated hydroxytoluene):

2.6-Di-*tert*-butyl-4-methylphenol,$C_{15}H_{24}O$

Description:

Solubility: TS (750~)

Melting temperature: 70 °

Sulfated ash: 1.0

RS (Calcium folinate):

TS ethanolic (**Ca** **100**) **Calcium standard**:

Procedure: 100.0 A 10)

TS (Ca TS (750~) 1000.

(**Ca** **10**) **Calcium standard**: **TS**

Procedure: 2.50 R2 15

1000 10.0 .(A 1000 TS (300~)

R (Calcium sulfate) $CaSO_4,2H_2O$ (SRIP 1963 62)

R (Calcium sulfate,hemihydrate):

$CaSO_{4,1/2}H_2O$, Plaster of Paris.

Description: porous.

TS (Calcium sulfate):

Procedure: 5 ... 100 ...

RS (Carbamazepine):

RS (Carbidopa):

R (Carboxymethylcellulose):

R (Cephaeline hydrochloride): $C_{28}H_{38}N_2O_4,2HCl,7H_2O$.

Description:

Specific optical rotation: 20 ... $[\alpha]_D^{20°C} = +25°$.

VS (0.1) Ceric sulfate:

Procedure: 33.23 ... $Ce(SO_4)_2$ ... 28 ... TS (~1760) ... 500 ... 1000 ... 48 ...

Method of standardization: 0.1 ... 25 ... 80 ... 10 ... TS (~105) ... 2.5 ... 1 ... VS (0.1) ... 15 ... TS.

RS (Chloramphenicol palmitate):

R (4-Chloraniline): 4- ... C_6H_6ClN.

Description:

Melting temperature: 70 °.

R (4-Chloroacetanilide) 4-: C_8H_8ClNO.

Description:

.R ƘǪɟ̊ąȘ TS (ȯ/ȟ750~) ȯȤǫǅ̊ǭɋ Ž ā̊ąȘǽ ǛȯÅ̊ţ Ž ǞȲȽȝ ā̊ąȘǽ ɍ :*Solubility ǦǭɟąȘǾȫ*

.ǞǤǞÅ̈Ŏǩ °ÿ 180 :*Melting temperature ǿÅ̊ȚÔɸɍ̊ ǦȴǿǺ*

.ǦȄȯȘǻ ǦȄǝÅ̊ȄȽȄȭ ǦȄǓȴÅ̈ɳ ǥǻÅ̊ɳ :**RS (Cimetidine)** ȸÅǢǭȄȽȄÊȯą

.(69 ǦǶÅ̇Ôȯą Û1963 ÛSRIP) $C_{19}H_{22}N_2O$:**R (Cinchonine)** ƘɸȤȮǞȄÊȯą

. î Å̊ȍÅ̈ȯą ȸɳ ɸ̇Å̊ǹ R Ȭ̃ÅǞǪȄÊȯą Ȑ̀ ƥ :**PbR (Citric acid)** Ȭ̃ÅǞǪȄÊȯą Ȑ̀ ƥ

.ǦȄȯȘǻ ǦȄǝÅ̊ȄȽȄȭ ǦȄǓȴÅ̈ɳ ǥǻÅ̊ɳ :**RS (Clofazimine)** ƘɛàÅ̊ȤȤŸȮȯą

.ǦȄȯȘǻ ǦȄǝÅ̊ȄȽȄȭ ǦȄǓȴÅ̈ɳ ǥǻÅ̊ɳ :**RS (Clomifene citrate)** ƘÅ̇ȄɳȤŸȮȯą ğąÅ̈ǪȄè

Å̈ȚɸąĄ .ǦȄȯȘǻ ǦȄǝÅ̊ȄȽȄȭ ǦȄǓȴÅ̈ɳ ǥǻÅ̊ɳ :**RS (Clomifene citrate Z-isomer)** ƘÅ̇ȄɳȤŸȮȯą ğąÅ̈ǪȄÊȯ **Z-**ȟȘÅ̊Ôţą .**RS** ƘÅ̇ȄɳȤŸȭȘà

.(70 ǦǶÅ̇Ôȯą Û1963 ÛSRIP) $CoCl_2,6H_2O$ ÜǨȯÅ̊ǽȤȮȯą ǼǞǿȤŸȭ :**R (Cobalt (II) chloride) II** ǨȯÅ̊ǽȤȮȯą ǼǞǿȤŸȭ

.189 ǦǶÅ̇Ôȯą ÛȯȘɟ̊ą ǼŸŎȯ Ž Å̈Îɸ Å̊ɳ ŌÛǤǞ ƂÅ̊Σą Ȍ̀Åȯą

ȟ 30 ǦǽąÅ̈ę ɁŸȝ ɃȤǪƷ ǨȯÅ̊ǽȤȮȯą ǼǞǿȤŸȮȯ ȯȤŸȚ :**TS (ȯ/ȟ30) (Cobalt (II) chloride) II** ǨȯÅ̊ǽȤȮȯą ǼǞǿȤŸȭ .Å̈ǪŸȯą Ž $CoCl_2$ ȸɳ

ȸɳ ȟ 5 ǦǽąÅ̈ę ɁŸȝ ɃȤǪƷ ǨȯÅ̊ǽȤȮȯą ǼǞǿȤŸȮȯ ȯȤŸȚ :**TS (ȯ/ȟ5) (Cobalt (II) chloride) II** ǨȯÅ̊ǽȤȮȯą ǼǞǿȤŸȭ .Å̈ǪŸȯą Ž $CoCl_2$

:**TS (Cobalt (II) chloride) II** ǨȯÅ̊ǽȤȮȯą ǼǞǿȤŸȭ

Ȑ̀ ƥ ȸɳ Ōɳ 2.5 ȸɳ ǰǞÂɳ ȸɳ ǦȄȤÅ̊ȭ ǦȄȽȭ Ž R (II) ǨȯÅ̊ǽȤȮȯą ǼǞǿȤŸȭ ȸɳ ȟ 6.5 ā̊ąǾǞ :*Procedure ȫąÅ̈ǱɋąÅ̈*

.Ōɳ 100 ǯÅ̊Ǫɸɋ ȫÅ̊ţą ȸɳ Ōɳ 97.5Ș TS (ȯ/ȟ250~) Ȭ̃ǞǿȤŸȭȘǿǼȄȚą

.328 ǦǶÅ̇Ôȯą Û2 ǼŸŎȯ Ž Å̈Îɸ Å̊ɳ ŌÛǤǞ ƂÅ̊Σą Ȍ̀Åȯą

.$Co(NO_3)_2,6H_2O$:**R (Cobalt (II) nitrate)** ǨȯÅ̊ǽȤȮȯą ğąÅ̈Ǫɸ

.ǥƘ8ȍ ȫąÅ̈ƥ ğąǿȤŸǽ :*Description ȤȍȤȫą*

.ȫÅ̊ţą Ž ǞǼǱ ā̊ąȘǽ :*Solubility ǦǭɟąȘǾȫ*

ɁŸȝ ɃȤǪƷ R (II) ǨȯÅ̊ǽȤȮȯą ğąÅ̈Ǫɸ ȸɳ ȯȤŸȚ :**TS (ȯ/ȟ100) (Cobalt (II) nitrate) (II)** ǨȯÅ̊ǽȤȮȯą ğąÅ̈Ǫɸ .Å̈ǪŸȯą Ž $Co(NO_3)_2$ ȸɳ ȟ100 ǦǽąÅ̈ę

:**TS (ȯ/ȟ10) (Cobalt (II) nitrate) (II)** ǨȯÅ̊ǽȤȮȯą ğąÅ̈Ǫɸ

.Ōɳ 100 ǯÅ̊Ǫɸɋ ȫÅ̊ţą ȸɳ ǦȄȤÅ̊ȭ ǦȄȽȭ Ž R (II) ǨȯÅ̊ǽȤȮȯą ğąÅ̈Ǫɸ ȸɳ ȟ 1.6 ǦǽąÅ̈ę ā̊ąǾǞ :*Procedure ȫąÅ̈ǱɋąÅ̈*

.ǦǁǬşǻ ǦǁǝǺǁƪǁǑ ǦǁǨǅǍǺŋ ǵǻŋ :**RS (Colchicine)** ƙÊǁÎǒǷǑǒǎ

50 ǦǎǍǺę ɁǛɜ ɃǷǪʒ R (II) âǺǶǺǒǎ ğǺǪǁèɉ ǒǷǛŢ :**TS** (ǒ/ȟ**45)** **(Copper (II) acetate) (II)** âǺǶǺǒǎ ğǺǪǁèǕ

.ǺǪǛǒǎ Ž $C_4H_6CuO_4,H_2O$ ȸŋ ȟ

.$CuCl_2,2H_2O$:**R (Copper (II) chloride) (II)** âǺǶǺǒǎ ǼǺǿǷǛǑ

.ǦȩǿÂǒǎ БǕ ǦǎǿǺȑ ǒǎǺȒǹ Ǧɜǵǁŋ ğǎǿǷǛǎ :*Description* Ȥòǵǒǎ

.R Ʀǫɉǎ Ž ȷǺǽşǾǒǎ ǴǁǶǹ ǕTS (ǒ/ȟ750~) ǒǷǹǺǯǺqǎ Ž āǎşǽ ǕǒǺţǎ Ž ȷǺǽşǾǒǎ Ǻǵ :*Solubility ǦǁǷǺǽşǾǒǎ*

:**TS (Copper (II) chloride/ammonia)** ǺǁǹǷŋɉǎ/**(II)** âǺǶǺǒǎ ǼǺǿǷǛǑ

ȸŋ Ǭŋ 100 ȣǺȒǺş ǒǺţǎ ȸŋ Ǭŋ 200 Ž R (II) âǺǶǺǒǎ ǼǺǿǷǛǑ ȸŋ ȟ 22.5 āǎǾǺ :*Procedure ǒǎǺǅǍqǎ*

.TS (ǒ/ȟ260~) ǺǁǹǷŋɉǎ

:**TS (Cu** Ǭŋ/ȳǎǺȡşǺǑǁŋ**10)** **Copper standard** ɃǿǺǁǨţǎ âǺǶǺǒǎ

ȤǺƸş ǕǬŋ 100 ǯǺǪǹq ǒǺţǎ ȸŋ ǦǁǷǺǑ ǦǁƪǑ Ž R (II) âǺǶǺǒǎ ğǺǺǛè ȸŋ ȟ0.393 āǎǾǺ :*Procedure ǒǎǺǅǍqǎ*

.Ǭŋ 1000 ǯǺǪǹq ǒǷǛǂǎ ǎǾȽ ȸŋ Ǭŋ 10.0

:**TS1 (Copper standard)** ɃǿǺǁǨţǎ âǺǶǺǒǎ

Ȓƥ ȸŋ ǦǁǷǺǑ ǦǁƪǑ Ž ǕǦǁùǷǦȒŋ ǦǹşǹǷŋ ǕR (II) âǺǶǺǒǎ ğǺǺǛè ȸŋ ȟ 1.965 āǎǾǺ :*Procedure ǒǎǺǅǍqǎ*

.Ǭŋ 1000 ǯǺǪǹq VS (ǒ/ǒǷŋ 0.1) ȬǺǿǷǛǑşǿǼǁŢǎ

:**TS2 (Copper standard)** âǺǶǺǒǎ ǿǺǁǨŋ

(ǒ/ǒǷŋ 0.1) ȬǺǿǷǛǑşǿǼǁŢǎ ȒƪШ ȤǺƸş Ǭŋ 1000 ǺǮǪǨè ǦǛǍǷǵ БǕ TS1 âǺǶǺǒǎ ǿǺǁǨŋ ȸŋ Ǭŋ 3.0 ǑǬǺ

.ǺǪǒ ɄǛǁţǎ Ž âǺǶǺǒǎ ȸŋ ȳǎǺȡşǺǑŋ 1.5 ɁǛɜ ǒǷǛǂǎ ǎǾȽ ɃǷǪʒ .Ǭŋ 1000 ǯǺǪǹq VS

ȸŋ ȟ 1 ɁǛɜ ɃǷǪʒ R (II) âǺǶǺǒǎ ğǺǺǛÊǒ ǒǷǛŢ :**TS** (ǒ/ȟ**1)** **(Copper (II) sulfate) (II)** âǺǶǺǒǎ ğǺǺǛè

.ǺǪǛǒǎ Ž $CuSO_4$

.$C_{21}H_{18}O_5S$:**R (Cresol red)** ǒşÂǺǺǑǒǎ ǵǺƥ

.ɄǿǺǦǒǎ БǕ āǿǺȑ ǺƥǕ ȧǷǶÊŋ :*Description Ȥòǵǒǎ*

ğǎǼǁÊǑşǿǼǁŢǎ ǑǁǒǺǂǎ Žş TS (ǒ/ȟ750~) ǒǷǹǺǯǺqǎ Ž āǎşǽ ǕǒǺţǎ Ž ȷǺǽşǾǒǎ ǴǁǶǹ :*Solubility ǦǁǷǺǽşǾǒǎ*

.ǦǺǺǺţǎ ǦǺǷǛǑǒǎ

:**TS (Cresol red/ethanol)** ǒǷǹǺǯǺqǎ/ǒşÂǺǺǑǒǎ ǵǺƥ

ȳǷǺǻǷÔǒǎ ǼǁÊǑşǿǼǁȽ ȸŋ Ǭŋ 2.65 ɜŋ R ǒşÂǺǺǑǒǎ ǵǺƥ ȸŋ ȟ0.05 ùǷǼǂ :*Procedure ǒǎǺǅǍqǎ*

TS (ȯ/ȟ150~) ȯɀɸȦ̆ǯȾqǟ ȣȦȒȾ Ûȯɀǐǂǟ Ȁǭǚǩ ǼȞǽ ÜTS (ȯ/ȟ710~) ȯɀɸȦ̆ǯȾqǟ ȸȠ Ōȵ 5ş VS (ȯ/ȯɀȵ 0.05)
.Ōȵ 250 ǯȦǪɸq ǦȨɀȦõ ǦȨȶȮǣ

:(Culture medium Cm8) Cm8 ţøÂǟǟ Ǜèş

ȯşƙÊǨǛȣǟǟ ȸȠ ȟ 10ş R ȀŌǦǟǟ ȴΣ ǦòŸǹ ȸȠ ȟ 10ş R ȤȦŎǟ ȷɀǪǦǦǟǟ ȸȠ ȟ 10 ǟǟØȾ :*Procedure ǒǟȀDZqǟ*
ǴǶÔȴ .Ōȵ 1000 ǯȦǪɸq ǒȦţǟ ȸȠ ǦȨɀȦõ ǦȨȶõ Ž R øȦɖɇǟ ȸȠ ȟ 17ş R ȳɀȾáɀÔǟǟ ǼȾøɀǐõ ȸȠ ȟ 3.0ş R
121 ǥøǟȀǵ ǦDZøǼǣ ǥǼòɀţȦǣ ȴŌȞȾş Û7.1-6.9 ɁøǪǵ VS (ȯ/ȯɀȵ 0.05) ȳɀȾáɀÔǟǟ ǼȨÊõşøǼȨȽ ǦùȦèɀǣ ǒȦȽȦǦǟǟ
.ǦŌȨęå 20-18 ǥǼȵ °ȳ

:(Culture medium Cm9) Cm9 ţøÂǟǟ Ǜèş

R ȯşȀÊǨǛȣǟǟ ȸȠ ȟ 10ş R ȀŌǦǟǟ ȴΣ ǦòŸǹ ȸȠ ȟ 10ş R ȤȦŎǟ ȷɀǪǦǦǟǟ ȸȠ ȟ10 ǟǟØȾ :*Procedure ǒǟȀDZqǟ*
ǼȨÊõşøǼȨȽ ǦùȦèɀǣ ǒȦȽȦǦǟǟ ǴǶÔȴ .Ōȵ 1000 ǯȦǪɸq ǒȦţǟ ȸȠ ǦȨɀȦõ ǦȨȶõ Ž R ȳɀȾáɀÔǟǟ ǼȾøɀǐõ ȸȠ ȟ 3.0ş
.ǦŌȨęå 20-18 ǥǼȵ °ȳ 121 ǥøǟȀǵ ǦDZøǼǣ ǥǼòɀţȦǣ ȴŌȞȾş Û7.1-6.9 ɁøǪǵ VS (ȯ/ȯɀȵ 0.05) ȳɀȾáɀÔǟǟ

:(Culture medium Cm10) Cm10 ţøÂǟǟ Ǜèş

R ȳɀȨǪɀȵɉǟ ǧǟȀǪ ȸȠ ȟ 5ş R ǒȦţǟ Ž ǦǟǟşØǟǟ ǥƘȶƪǟ ǦòŸǹ ȸȠ ȟ 1 ǟǟØȾ :*Procedure ǒǟȀDZqǟ*
ȸȠ ǦȨɀȦõ ǦȨȶõ Ž R øȦɖɇǟ ȸȠ ȟ 14ş R ȰəȦȵŸǟǟ àɀõɀǛȣǟǟ ȸȠ ȟ 5ş R ƙDZşøǼȨȚǟ ȰəȦǪ ǧȦȀèɀɀ ȸȠ ȟ 5ş
.Ōȵ 1000 ǯȦǪɸq ǒȦţǟ

:(Culture medium Cm11) Cm11 ţøÂǟǟ Ǜèş

Ž R øȦɖɇǟ ȸȠ ȟ 15ş R ȀŌǦǟǟ ȴΣ ǦòŸǹ ȸȠ ȟ 6ş R ȤȦŎǟ ȷɀǪǦǦǟǟ ȸȠ ȟ10 ǟǟØȾ :*Procedure ǒǟȀDZqǟ*
ÛVS (ȯ/ȯɀȵ 1) ȳɀȾáɀÔǟǟ ǼȨÊõşøǼȨȽ ǦùȦèɀǣ ȯɀǐǂǟ ǒȦȽȦǣ ǴǶÔȴ .Ōȵ 1000 ǯȦǪɸq ǒȦţǟ ȸȠ ǦȨɀȦõ ǦȨȶõ
ÛǸȨɀȦò ǴǦÔȾ ɁøǪǵ ǥøşȀȒǟǟ ǼȾȝ ÛǴìȀȴ .7.8 ȴŌȞţǟ Ǜèɀǟǟ Žş ǦȀȦȚȀǟǟ ǼȾȝ ǒȦȽȦǦǟǟ ǴǦÔǩ ȷǕ Ƃǔ ÛǥøşȀȒǟǟ ǼȾȝ
.ǦŌȨęå 20-18 ǥǼȵ °ȳ 121 ǥøǟȀǵ ǦDZøǼǣ ǥǼòɀţȦǣ ȴŌȞȾş ǦȶəŸȵ ǦȨȝşǔ Ž ȯɀǐǂǟ ţàɀȾ

.ǦȨşå ǦȨəȦȨȶȨõ ǦȨȞDZȀȵ ǥåȦȵ :**RS (Cytarabine)** ƙǟǟøȦǪȨè

.ǦȨşå ǦȨəȦȨȶȨõ ǦȨȞDZȀȵ ǥåȦȵ :**RS (Dexamethasone sodium phosphate)** ȷşȀǪȨȵȦÊÔȾǼǟǟ ȳɀȾáɀò ǧȦȀèɀɀ

.ǦȨşå ǦȨəȦȨȶȨõ ǦȨȞDZȀȵ ǥåȦȵ :**RS (Dextromethorphan hydrobromide)** ȷȦɀøɀǯȨȵşȀǪÊÔȾå ǼȨȵşȀǣşøǼȨȽ

:R (Diatomaceous support) ǧǟøɀÛÎţǟ ȳȦɜå

ǥåȦţǟ ȷɀÔǪǩ .ǧǟøɀÛÎţǟ ŌõȦȨȽ ȸȠ ȯşɉǟ ȳȦŌţǟ Ž ȤǟǚǪǩ ȦÔǨǛÊǟǟ ȸȠ ǒȦȒȨǣ ǧȦǦǦǵ :*Description ȤòɀǟǟǕ*
ǥåɀDZɀȵ ȰȽş ÛȷɀǛǟǟ ǇǼɜ ŌÔì Ž flux-calcined ǦǛȨÊȵ ǦȀÊǛÔȵ Ƃǔ ǦǪɀǛȵ ǦõşȀǶȵ ǦȨɸǼǶȵ ǧǟǼȨÊõşǔ ȸȠ

[illegible] Silanized [illegible] acid-washed [illegible]
[illegible] alkali-washed [illegible].

[illegible] **R (Dichlorofluorescein)**: $C_{20}H_{10}Cl_2O_5$.

Description [illegible]: [illegible].

Solubility [illegible]: [illegible] (~750 [illegible]) TS.

[illegible] **TS (Dichlorofluorescein)**:

Procedure [illegible]: 0.2 [illegible] R [illegible] 100 [illegible] R.

[illegible] **RS (Dicloxacillin sodium)**: [illegible].

[illegible] **R (Diethylaminoethylcellulose)**: [illegible].

[illegible] **R (Diethyl phthalate)**: $C_{12}H_{14}O_4$.

Mass density [illegible]: 1.117 $\rho_{20} =$ [illegible].

Refractive index [illegible]: $n_D^{20} = 1.500 - 1.505$.

[illegible] **RS (Diloxanide furoate)**: [illegible].

[illegible] **R (Dimethylacetamide)**: C_4H_9NO.

Description [illegible]: [illegible].

Boiling temperature [illegible]: 165 °[illegible].

Mass density [illegible]: 0.94 $\rho_{20} =$ [illegible].

[illegible]-4 **TS5 (4-Dimethylaminobenzaldehyde)**:

Procedure [illegible]: 2 [illegible]-4 R [illegible] 45 [illegible] 55 [illegible] (~420 [illegible]) TS.

[illegible]-4 **TS6 (4-Dimethylaminobenzaldehyde)**:

Procedure [illegible]: 0.2 [illegible]-4 R [illegible] 20 [illegible] (~750 [illegible]) TS [illegible] 0.5 [illegible] (~420 [illegible]) TS [illegible] R [illegible] (0.0001 [illegible]) VS.

[illegible]: [illegible]-4 TS6 [illegible].

N,N-Dimethylaniline R: $C_8H_{11}N$.

Description:

Miscibility: (~750 g/l) TS R R.

Boiling temperature: 193 °C.

Mass density: ρ_{20} =0.96 g/ml.

Dimethyl sulfoxide R: C_2H_6OS.

Description:

Mass density: ρ_{20} = 1.10 g/ml.

2,4-Dinitrochlorobenzene R: $C_6H_4ClN_2O_4$ (PIRS 1963, 80).

Diphenoxylate hydrochloride RS:

Diphenylamine/sulfuric acid TS:

Procedure: 1.0 g R 100 ml (~1760 g/l) TS.

Storage: TS

1.5-Diphenylcarbazide R: $C_{13}H_{14}N_4O$.

Description:

Melting temperature: 174 °C.

Diphenylcarbazide TS:

Procedure: 0.2 g 1,5-Diphenylcarbazide R 10 ml 90 ml R (~710 g/l) TS.

Sensitivity test to chromate: 0.5 ml (0.0167 mol/l) VS 1000 ml. 5 ml 50 ml 0.2 ml (2 mol/l) VS 0.5 ml TS.

Disodium edetate (20 g/l) TS: R 20 g $C_{10}H_{14}N_2Na_2O_8$.

Disodium edetate (10 g/l) TS: R

$C_{10}H_{14}N_2Na_2O_8$ 10

VS (0.01) (Disodium edetate)

1000 $C_{10}H_{14}N_2Na_2O_8$ 3.342

Method of standardization

194 1 VS (0.05)

TS (100) (Disodium hydrogen phosphate)

Na_2HPO_4 100 R

TS (28.4) (Disodium hydrogen phosphate)

Na_2HPO_4 28.4 R

TS (Dithizone standard)

R 1000 R 10 *Procedure*

Storage

4 °

TS (Dithizone)

TS (~750) R 0.10 *Procedure*

100

RS (Dopamine hydrochloride)

RS (Doxorubicin hydrochloride)

RS (Emetine hydrochloride)

$C_{20}H_6Br_4N_2O_5$ R (Eosin Y) Y

Description

TS (~750) *Solubility*

$C_{20}H_6Br_4Na_2O_5$ 5 Y TS (5) (Eoson Y) Y

RS (Ergocalciferol)

$C_{28}H_{44}O$ ergosta-5,7,22-trien-3-ol ;D_2 R (Ergosterol)

%95.0 $C_{28}H_{44}O$

[illegible] :*Description* [illegible]

[illegible] °ÿ 163 [illegible] :*Melting temperature* [illegible]

[illegible] 20 [illegible] :*Specific optical rotation* [illegible]

$[a]_D^{20C°} = -133°$ [illegible]

[illegible] :**RS (Erythromycin)** [illegible]

[illegible] :**RS (Erythromycin ethylsuccinate)** [illegible]

[illegible] :**RS (Erythromycin stearate)** [illegible]

[illegible] :**RS (Ethionamide)** [illegible]

$C_3H_8O_2$ [illegible]-2 :**R (Ethylene glycol monomethyl ether)** [illegible]

[illegible] :*Description* [illegible]

°ÿ 125 :*Boiling temperature* [illegible]

[illegible] ρ_{20} = [illegible] 0.96 :*Mass density* [illegible]

:**VS** ([illegible] **0.1**) **(Ferric ammonium sulfate)** [illegible]

[illegible] TS ([illegible] 1760~) [illegible]

[illegible] 1000 [illegible] $FeNH_4(SO_4)_2,12H_2O$ [illegible] 48.22

[illegible] 6 [illegible] 300 [illegible] R [illegible] 50 [illegible] :*Procedure* [illegible]

[illegible] 1000 [illegible] TS ([illegible] 1760~) [illegible]

[illegible] 0.1 [illegible] :*Method of standardization* [illegible]

[illegible] 3 [illegible] 25 [illegible]

[illegible] 10 [illegible] R [illegible] 2 ([illegible] 420~)

[illegible] VS ([illegible] 0.1)

[illegible] :*Storage* [illegible]

[illegible] $FeCl_3$ [illegible] 65 [illegible] :**TS** ([illegible] **65**) **(Ferric chloride** [illegible]

[illegible]

$FeCl_3$ [illegible] 50 [illegible] :**TS** ([illegible] **50**) **(Ferric chloride)** [illegible]

[illegible]

:**TS (Ferric chloride/ferricyanide/arsenite)** ǨȄȄèǿǕ/ȄȄȍȄȄè ɃǨȥ/ȭȿǨǺȍȁ Ȅȿǿȥǜȭ

:ǦǛǑǺȿȵ ǬȄȍǺȚ ǦǭɎǭ ǸȒƠ :*Procedure ǒǡǞǻǬq*

.TS (ȯ/ȟ70~) ȭȿǿȥǜȭȿǿȄȄȚȁ Ȑ ƥ ȸȵ ǬȵȵȲ 100 Ž R ȭȿǨǺȍȁ Ȅȿǿȥǜȭ ȸȵ ȟ 2.7 ǡǡǾȿ (1)

.ȂǬǞǻǚǺǜ ȯȥǛƗǡ ǡǾȽ ǨȒƠ Ǣƶ .ǒǺȵ ǬȵȵȲ 100 Ž R ƴȥȄèǺǩȥǦȍȁ ȄȄȍȄȄè ɃǨȥ ȸȵ ȟ 3.5 ǡǡǾȿ (2)

.TS (ȯ/ȟ80~) ȸǺȆȶȁ ƴȥȿǻȥǑȍȁ ȄȄȆȭȿǿȄȽ ȸȵ ǬȵȵȲ 25 Ž R ȭȄȄèǿɉǡ ȄȄȆȭǕ ɄǭɎǭ ȸȵ ȟ 3.8 ǡǡǾȿ (3)

.ǒǺȶǺǽ ǬȵȵȲ 100 ƂǕ ȤǺƩȿ ǛTS (ȯ/ȟ100~) ȭȿǿȥǺǜȆȍȁ Ȑ ƥ ȸȵ ǬȵȵȲ 50 ȣǺȒȿ ǛǻƎȄǑ ȭǺǭȿ

.(3) ȯȥǛƗǡ ȸȵ ȄǵǡȿȘ ǈǞȥǵȿȘ (2) ȯȥǛƗǡ ȸȵ ƴȥǞȥǵ 5ȿ (1) ȯȥǛƗǡ ȸȵ ƴȥǞȥǵ 5 ȝǺȿ ƴǡȄȀǭèɍǡ ǬǦȩ ǥǺȉǺǦȵ

:**TS (Ferric chloride/potassium ferricyanide)** ƴȥȄèǺǩȥǦȍȁ ȄȄȍȄȄè ɃǨȥ/ȭȿǨǺȍȁ Ȅȿǿȥǜȭ

ǦȄȥǺȭ ǦȄȶȭ Ž R ƴȥȄèǺǩȥǦȍȁ ȄȄȍȄȄè ɃǨȥ ȸȵ ȟ 0.10ȿ R ȭȿǨǺȍȁ Ȅȿǿȥǜȭ ȸȵ ȟ 2 ǡǡǾȿ :*Procedure ǒǡǞǻǬq*

.ǬȵȵȲ 20 ȝǺǬȍq ǒǺȶǡ ȸȵ

.ȂǬǞǻǚǺǜ TS ƴȥȄèǺǩȥǦȍȁ ȄȄȍȄȄè ɃǨȥ/ȭȿǨǺȍȁ Ȅȿǿȥǜȭ ǨȒƠ Ǣƶ :*ǦȚǵɎȵ*

:**TS** (Ǭȵ/ƴǡǺȡȿǺǬȵ **50**) **(Ferricyanide standard)** ɃǿǺȄȞȶǡ ȄȄȍȄȄè ɃǨǺȍȁ

Ž K$_3$Fe(CN)$_6$ ȸȵ ȟ 7.8 ɁǛȝ ɃȥǬƷȿ ǒǺȶǡ Ž R ƴȥȄèǺǩȥǦȍȁ ȄȄȍȄȄè ɃǨȥ ȯȥǛȚ ǸȒƷ :*Procedure ǒǡǞǻǬq*

.ǬȵȵȲ 1000 ȝǺǬȍq ǒǺȶǡ ȸȵ ǦȄȥǺȭ ǦȄȶǑȁ ȯȥǛƗǡ ǡǾȽ ȸȵ ǬȵȵȲ 1.0 ȤǺƩ .ǬȵȵȲ 100

.ȂǬǞǻǚǺǜ (Ǭȵ/ƴǡǺȡȿǺǬȵ 50) ɃǿǺȄȞȶǡ ȄȄȍȄȄè ɃǨǺȍȁ ǨȒƠ Ǣƶ :*ǦȚǵɎȵ*

:**TS** (Ǭȵ/ƴǡǺȡȿǺǬȵ **100**) **(Ferrocyanide standard)** ɃǿǺȄȞȶǡ ȄȄȍȄȄèȿǨǺȍȁ

K$_4$Fe(CN)$_6$,3H$_2$O ȸȵ ȟ 2.0 ɁǛȝ ɃȥǬƷȿ ǒǺȶǡ Ž R ƴȥȄèǺǩȥǦȍȁ ȄȄȍȄȄèȿǨȥ ȯȥǛȚ ǸȒƷ :*Procedure ǒǡǞǻǬq*

.ǬȵȵȲ 100.0 ȝǺǬȍq ǒǺȶǡ ȸȵ ǦȄȥǺȭ ǦȄȶǑȁ ȯȥǛƗǡ ǡǾȽ ȸȵ ǬȵȵȲ 1.0 ǻȄȝ .ǬȵȵȲ 100 Ž

.ȂǬǞǻǚǺǜ (Ǭȵ/ƴǡǺȡȿǺǬȵ 100) ɃǿǺȄȞȶǡ ȄȄȍȄȄèȿǨǺȍȁ ǨȒƠ Ǣƶ :*ǦȚǵɎȵ*

.ǦȄǒȿǻ ǦȄȞǞǻǺȵ ǦȄȍǺȄȶȄȭ ǥǻǺȵ :**RS (Flucytosine)** ȸȿǡȥȄǬȄèȥǜǺȍȁ

.ǦȄǒȿǻ ǦȄȞǞǻǺȵ ǦȄȍǺȄȶȄȭ ǥǻǺȵ :**RS (Fludrocortisone acetate)** ȷȿǺȿǿȥȭȿǿǻȥǜǺȍȁ ǧǺǬȄèǕ

.ǦȄǒȿǻ ǦȄȞǞǻǺȵ ǦȄȍǺȄȶȄȭ ǥǻǺȵ :**RS (Fluorouracil)** ǬȄèǡǿȥȿȿǿȥǜȥ

.ǦȄǒȿǻ ǦȄȞǞǻǺȵ ǦȄȍǺȄȶȄȭ ǥǻǺȵ :**SV RS (3-Formylrifamycin)** ƙȆȄǦȄȵǺȿǿ ǬȄȵǿȥȥ-**3**

:**TS (Fuchsin,decolorized)** ȷȥǜȍȁ ȯǡǺȵ ǛƙȆȭȥǺȍȁ

ȣǺȒȿ ǛȄȄǜǞ ƴǺƥ Ž ǻƎȿȿ ǒǺȶǡ ȸȵ ǬȵȵȲ 600 Ž basic ɄèǺèɉǡ ƙȆȭȥǺȍȁ ȸȵ ȟ 1 ǡǡǾȿ :*Procedure ǒǡǞǻǬq*

ǛǺȶǬȆȶǡ ȭȿǺȞǬȍȁ ȝȵ ǛǒǛǦ ȣǺȒȿȿ ȄȄǜǞ ƴǺƥ Ž ǻƎȿ ǛǒǺȵ ǬȵȵȲ 100 Ž ǦǒȥǜȚ R ƴȥȿǻȥǑȍȁ ǨȄǺǜè ȸȵ ȟ 20

ãæÛ ǰǩÅÄöã ȯȥŸǂã ǴĽìÀǩ Ǣƶ .Ǿŋ 1000 ƁÛ ŏÅţÅæ ȤÀƸ ÛTS (ȯ/ȟ250~) ȬÃøȥŸȭşøǼĽTã Ȑƥ ȸŋ Ǿŋ 10
ÛȷȥŸöã ȻǼȝ åȥȞÃ ʔøǪǵ (ȟ 0.3-0.2) R ȴĦÀöã ȸŋ ǦĽȥÅȭ ǦĽȶȭ Ȝŋ ȼǷǅø Ǣƶ ÛĦĽÃæ ȼǪȥö ȷÅȭ ãæÛş ÛĦÃÒȝ ȷÅȭ
ÛTS (ȯ/ȟ250~) ȬÃøȥŸȭşøǼĽTã Ȑƥ ȸŋ Ǿŋ 3-2 ǦȥÅȑÛ ÛĦǪÅĽǵÛ Ƀøş ÀȒöã ȸŋ ȷȥÒÃ Ǽȩ .ǥÀìÅǤŋ ǴǹìÀÃ Ż
ǦȪæÅÊöã ǧƳÃǼȞǪöã ȸŋ ɃÛ ȸȝ ǰǩÅÄöã ȯȥŸǂã ȫÃǩ Ǣƶ .ǼȽÅÎöã ȷȥö ȸŋ ɄǷǦǪţã ȪĽŸȪöã ǦöãàƣÛǯÀöã Ȭöæ ȜǤǪÃ
.öȥȒöã ȸŋ ʔȶȜ ȷÛ Ǣƶ TS ȷȥŸöã ȯãÀŋ ƙÊȭȥÀöã .ȳãǼǺǪèɍã ȪǤȩ ȪĽŸöã ȯãȥü ÀȬǪÊĽö

.ǦĽöşå ǦĽȞǅÀŋ ǦĽəÅĽȶĽȭ ǥåÅŋ :**RS (Gallamine triethiodide)** ƙŋƳ8öã ǼÃåȥĽȜÃÛ ɄǪƳǪ

.ǦĽöşå ǦĽȞǅÀŋ ǦĽəÅĽȶĽȭ ǥåÅŋ :**RS (Gentamicin sulfate)** ƙÊĽŋÅǪÃĽɞã ǧÅÃŸè

.ǦĽöşå ǦĽȞǅÀŋ ǦĽəÅĽȶĽȭ ǥåÅŋ :**RS (Glibenclamide)** ǼĽŋƳÒÃĽǤĽŸ8öã

.$C_6H_{12}O_6$:**R (Glucose,anhydrous)** ɄəÅŋƳöã ÛàȥȭȥŸ8öã

.150 ǦĦÀÔöã 2 ǼŸÕã Ž ǥåşÀȥɉã Ž 8ȥòȥŋ ȥȽ Åȶȭ ɄəÅŋƳöã àȥȭȥŸ8öã ȳǼǼǪÊÃ

.(94 ǦĦÀÔöã Û1963 ÛSRIP) C_7H_{16} :**R (Heptane)** ȷÅǪǤĽTã

.$C_6H_{19}NSi_2$:**R (Hexamethyldisilazane)** ȷããƳĽè ɄəÅǪ ȪĽȜĽŋ Ʉèãǿè

.ǥÅĽư ǦĦəãø ȼö ÛȷȥŸöã ȻǼȝ Û8Åò ȪəÅè :*Description* *Ȥòȥöã*

.ρ_{20} = ȯ/ŋȭ 0.77 :*Mass density* *ǦŸǪÒöã ǦȥÅȷȭ*

.$(NH_4)_2,H_2SO_4$:**R (Hydrazine sulfate)** ȸÃàãøǼĽTã ǧÅÃŸè

.ȐĽãÛ Ƀøȥæ ȧȥĦÊŋ şÛ .ȷȥŸöã ǦƸǼȝ ǧãøȥŸæ :*Description* *Ȥòȥöã*

.TS (ȯ/ȟ750~) ȯȥǪÅȜÃǭã Ž ĦĽŸȶȝ Ǧããşæ ƘȡÛĦǤÃÀǩ ŏÅţã ȸŋ ĦõÀǅ 40 Ž ȼããşæ :*Solubility* *ǦǷǪÅɜşǾöã*

øÅǤǪǹȑã" ȷãȥÅȝ ǨƠ 8ȥòȥŋ ȥȽ Åȶȭ ȜãÅǪÃş ɄŸ8ţã ŏÅţã ȸŋ Ǿŋ 35 Ž ȟ 10 ȯȥŸƮ ȳǼǼǪÊÃ :*Arsenic* *ǸĽǪøÂöã*
.ȟ/ȳãÀȡşÀÒŋ 1 ȸȝ ǼÃÅÃ ȑ Ü(130 ǦĦÀÔöã Û1 ǼŸÕã) "Limit test for arsenic ǸĽǪøÂöã ȮǅȤ ɃǼƩã

.ȟ/ŋŸŋ 1.0 ȸȝ ǼÃÅÃ ȑ :*Sulfated ash* *ǨÅŸÊţã åÅŋÀöã*

ÛöÅţã Ž TS (ȯ/ȟ420~) ȬÃøȥŸȭşøǼĽTã Ȑƥ :**TS (ȯ/ȟ330~) (Hydrochloric acid)** ȬÃøȥŸȭşøǼĽTã Ȑƥ
.(ȯ/ȯȥŋ 9 ǦããÅȩ) *d*~1.15 ÜÀǪŸöã Ž HCl ȸŋ ȟ 330 ǦããÅȩ Ƀȥȝ

ÛTS (ȯ/ȟ250~) ȬÃøȥŸȭşøǼĽTã Ȑƥ :**VS (ȯ/ȯȥŋ 0.05) (Hydrochloric acid)** ȬÃøȥŸȭşøǼĽTã Ȑƥ
.Ǿŋ 1000 Ž HCl ȸŋ ȟ 1.824 ȜȥǪƮ ʔøǪǵ ŏÅţÅæ ȤÀƯ

ǦȥȥòȥţãǦȪÃÀÛöã ţÅǤǨÅæ ȯȥŸĦȶŸö ȓȥǤȒţã ÂĽȭÀǪöã ȸŋ ǨǷǷǪöã ɃÀƶ :*Method of standardization* *ǥÅÅĦţã ǦȪÃÀü*
.200 ǦĦÀÔöã Û1 ǼŸÕã ÛVS (ȯ/ȯȥŋ 1) ȬÃøȥŸȭşøǼĽTã Ȑƥ ȷãȥÅȝ ǨƠ

ÛTS (ȯ/ȟ250~) ȬǀǿɀȲȭşǿǼȽȚ Ȑþ :VS (ȯ/ȯɀɳ **0.005**) **(Hydrochloric acid)** ȬǀǿɀȲȭşǿǼȽȚ Ȑþ

.Ȭɳ 1000 Ž HCl ȟ 0.1824 ɁɀǪƮ БǗ ǒȽţȽ ȤȦȨ

Ǧɀɀȍɀţ ǦȬȽÛ ţȽǦȽ ȯɀȲɄŧȲ ȓɀǦȒţ ȽȭȽǪ ȡɳ ȮǨǪ ɃȦƶ :*Method of standardization gȦȽȟţ ǦȬȽü*

.200 ǦɄȦÔ Û1 ǼȲǑ ÛVS (ȯ/ȯɀɳ 1) ȬǀǿɀȲȭşǿǼȽȚ Ȑþ ɉȽɀȜ ǨƠ

ȤȦȨ Û(ȯ/ȟ250~) ȬǀǿɀȲȭşǿǼȽȚ Ȑþ :VS (ȯ/ȯɀɳ **0.0001**) **(Hydrochloric acid)** ȬǀǿɀȲȭşǿǼȽȚ Ȑþ

.Ȭɳ 1000 Ž HCl ȡɳ ȠȲɳ 3.647 ɁɀǪƮ БǗ ǒȽţȽ

Ǧɀɀȍɀţ ǦȬȽÛ ţȽǦȽ ȯɀȲɄŧȲ ȓɀǦȒţ ȽȭȽǪ ȮǨǪ ɃȦƶ :*Method of standardization gȦȽȟţ ǦȬȽü*

.200 ǦɄȦÔ Û1 ǼȲǑ ÛVS (ȯ/ȯɀɳ 1) ȬǀǿɀȲȭşǿǼȽȚ Ȑþ ɉȽɀȜ ǨƠ

ȬǀǿɀȲȭşǿǼȽȚ Ȑþ :VS (ȯ/ȯɀɳ **0.01**) **(Hydrochloric acid/methanol)** ȯɀȽǰţ/ȬǀǿɀȲȭşǿǼȽȚ Ȑþ

.ȯɀȽǰţ ȡɳ Ȭɳ 1000 Ž HCl ȡɳ ȟ 0.3647 ɁɀǪƮ БǗ ȯɀȽǰţȽ ȤȦƯ ÛTS (ȯ/ȟ250~)

Ǧɀɀȍɀţ ǦȬȽÛ ţȽǦȽ ȯɀȲɄŧȲ ȓɀǦȒţ ȽȭȽǪ ȡɳ ȮǨǪ ɃȦƶ :*Method of standardization gȦȽȟţ ǦȬȽü*

.200 ǦɄȦÔ Û1 ǼȲǑ ÛVS (ȯ/ȯɀɳ 1) ȬǀǿɀȲȭşǿǼȽȚ Ȑþ ɉȽɀȜ ǨƠ

.ǦȽşǻ ǦȽȽŧȭ ǦȟǅȽɳ gȽɳ :**RS (Hydrocotisone sodium succinate)** ɉşȽǿɀȭşǿǼȽ ÿɀǻɀȍ ğȽȽȆȭɀȅ

.$C_6H_4(OH)_2$:**R (Hydroquinone)** ɉɀȽȭşǿǼȽ

.Ƀǿɀ ȧɀɄȆɳ şǗ ȽȽǑǨ ɉɀȲ ǦɛȜ şǗ ɉɀȲ ǦɛȜ ğȽǿɀ :*Description ȤȍɀȽ*

.R ǨǪɉȽş TS (ȯ/ȟ750~) ȯɀȽǰɋȽş ǒȽţ Ž ȃȽşǽ :*Solubility ǦȽȽşǾȽ*

.ȽȽȽǨ °ÿ 173 :*Melting temperature ǿȽȚÔɵɼȽ ǦǅǿȽ*

.ǒɀȒȽş ǒȽɀȚȲ ¢ȑȽȟȽ ɉɀȽȭşǿǼȽ ɉɀȽ ȴȭȽ :*ǦȚǵȲɳ*

:**TS (ȯ/ȟ200) (Hydroxylamine hydrochloride)** ƙɳɍ ɄȆȭşǿǼȽ ǼȽǿɀȲȭşǿǼȽ

.ȽǪȲȽ Ž NH_2OH,HCl ȡɳ ȟ200 ǦȽȽę Бɀȝ R ƙɳɍ ɄȆȭşǿǼȽ ǼȽǿɀȲȭşǿǼȽ ȯɀȲƮ

:**RS** ƙɸɍǗ ȬȽǯɳ-2-ɀȽȃȽǿǼȽ-2-(ȬȽȽɀ ɄȆȭɀǯɳ-3-ɄȆȭşǿǼȽ-4)-3-(-)

.ǦȽşǻ ǦȽȽŧȭ ǦȟǅȽɳ gȽɳ :**TS** Û**(-)-3-(4-Hydroxy-3-methoxyphenyl)-2-hydrazino-2-methylalanine**

.10,11-Dihydro-5*H*-dibenz[*b.f*]azepine; $C_{14}H_{13}N$:**R (Iminodibenzyl)** ȬȽÂǿȽ ɄȽȽǪ ɀȽȨǗ

.ǼǵȽȉ ȽȽȍǗ Ƀǿɀ ȧɀɄȆɳ :*Description ȤȍɀȽ*

.ȽȽȽǨ °ÿ 106 :*Melting temperature ǿȽȚÔɵɼȽ ǦǅǿȽ*

ǒȽȽ ȽȽǼȽǨ ǴȽǨ Ʉǿȱȣ ɉɀȲ ğȽȽȟȊɳ ȡɳ ǼȅȽɳ ǰȽɳ ȝɳ ȧǿş :**R (pH-Indicator paper)** ǒȽȽǦȽ ȽȟȊɳ ȧǿş

.10-1 Ƅấǚ ǒȦȽȦǽ ȯȦƒ Ž (ģấȦȝ ģǼǵǟş ǒȦȽȦǽ ģǼǵş) ǦŁȤȦǒ ǦĿèȦÊǵ ȝŋ ȷȤǛǟ ğɍǼǦǩ ȯɎǹ ȸŋ ȯȤǛǂǟ

:TS (Iodine/chloroform) ÿøȤȤşøȤǛȮǟ /ấȤĿǟ

.Ǒŋ 100 ǯȦǬɋ R ÿøȤȤşøȤǛȮǟ ȸŋ ǦŁȤȦǒ ǦĿȶǒ Ž ấȤȦ ȟ 5.0 ǡǟǾȦ :*Procedure ǒǟǞǽɋǟ*

I_2 ȟ 12.69 ȜȤǪȚ ȝøǪǵ ǒȦţǟ Ž ȷȦǟǾŋ ÛR ÿȤĿèȦǨȤǦǟ ǼȦấȤȦş R ấȤĿǟ **:VS (ȯ/ȯȤŋ 0.05) (Iodine)** ấȤĿǟ

.Ǒŋ 1000 Ž KI ȟ 18.0ş

ǦȤȤȍȤţǟ ǦǑȦȀÛǟ ţȦǦǨȦǽ ȯȤǛȞȶǛ ȓȤǦȒţǟ ȦĿǒȦǬǟ ȸŋ ǨǲǬǟ ȻȦẕ :*Method of standardization ģǞȦǶţǟ ǦǑȦǞü*

.202 ǦȞȦÔǟ Û1 ǼǛǑǟ ÛVS (ȯ/ȯȤŋ 0.1) ấȤĿǟ ȷǟȤȦȝ ǨƠ

ȟ 1.8ş I_2 ȟ 1.269 ȜȤǪȚ ƂǛ ǒȦţǟ Ž ȷȦǟǾŋ ÛR ÿȤĿèȦǨȤǦǟ ǼȦấȤȦş ấȤĿǟ **:VS (ȯ/ȯȤŋ 0.005) (Iodine)** ấȤĿǟ

.Ǒŋ 1000 Ž KI

ǦȤȤȍȤţǟ ǦǑȦȀÛǟ ţȦǦǨȦǽ ȯȤǛȞȶǛ ȓȤǦȒţǟ ȦĿǒȦǬǟ ȸŋ ǨǲǬǟ ȻȦẕ :*Method of standardization ģǞȦǶţǟ ǦǑȦǞü*

.202 ǦȞȦÔǟ Û1 ǼǛǑǟ ÛVS (ȯ/ȯȤŋ 0.1) ấȤĿǟ ȷǟȤȦȝ ǨƠ

I_2 ŋǛŋ 25.38 ȜȤǪȚ ȝøǪǵ ǒȦţǟ Ž ȷȦǟǾŋ ÛR ÿȤĿèȦǨȤǦǟ ǼȦấȤȦş R ấȤĿǟ **:VS (ȯ/ȯȤŋ 0.0001) (Iodine)** ấȤĿǟ

.Ǒŋ 1000 Ž KI ŋǛŋ 0.36ş

ǦȤȤȍȤţǟ ǦǑȦȀÛǟ ţȦǦǨȦǽ ȯȤǛȞȶǛ ȓȤǦȒţǟ ȦĿǒȦǬǟ ȸŋ ǨǲǬǟ ȻȦẕ :*Method of standardization ģǞȦǶţǟ ǦǑȦǞü*

.202 ǦȞȦÔǟ Û1 ǼǛǑǟ ÛVS (ȯ/ȯȤŋ 0.1) ấȤĿǟ ȷǟȤȦȝ ǨƠ

:TS (Iron salicylate) ǼȦǼƩǟ ğɎĿÊǟȦè

ȐƿȸŋǑŋ 10 ȻȤȜ ǒȦŋ ȸŋ Ǒŋ 250 Ž R ǬȦǨȦǟ ÿȤĿǫȤŋǚ ğȦȦǛè ȸŋ ȟ 0.5 ǡǟǾȦ :*Procedure ǒǟǞǽɋǟ*

ȯȤǛǂǟ ǟǾȽ ȸŋ Ǒŋ 100 ƂǚȢȦȒȦ .Ǒŋ 500 ǯȦǬɋ ǒȦţǟ ȸŋ ǦŁȤȦǒ ǦĿȶȮǟ ȤȦƩş ÛTS (ȯ/ȟ100~) ǬȦøȤȦǛÊǟ

ȸŋ Ǒŋ 80ş TS (ȯ/ȟ 60~) ǬĿǬèɉǟ Ȑƿ ȸŋ Ǒŋ 20ş ÛTS (ȯ/ȟ11.5) ÿȤȦấȤÔǟ ğɎÊǛè ȸŋ Ǒŋ 50

.Ǒŋ 500 ƂǚǒȦţȦǟ ȤȦƩş ÛTS (ȯ/ȟ150) ÿȤȦấȤÔǟ ğȦǬĿèǚ

.ǒȤȒǟ ȸŋ ȝȶȝş ÛǼǼǟǱ ǦǑǛȢŋ ǦȦşȦǵ Ž ȷȦƩ :*Storage ȸȦÂǺǬǟ*

.ǟǱǟȦü ǼȦǼƩǟ ğɎÊǟȦè ǨȒƠ Ǽẕ :*ǦȚǵɎŋ*

.C_3H_9N :R (Isopropylamine) ǩŋɎǟşȦǟÂȦɋǟ

.ǦȦøǟấȦÎɋ ǦȞǟǾø ȝŋ ȷȤǛǟ ǠǼȝ ÛøȦĿü ǑǟȦè :*Description ȤȍȤǟ*

.ǟǦȦǑǨ °ÿ 33 :*Boiling point* ȷȦɎǛȢǟ ǦÛǑɋ

.ǟǦȦǑǨ $\rho_{20} =$ ȯ/ŋǒ 0.69 :*Mass density ǦǛǪȮǟ ǦȤȦǩǒ*

:R (Lead acetate paper) î ÀòÀöä ğÀǬĘèǗ ȧǿş

TS (ȯ/ȟ80) î ÀòÀöä ğÀǬĘèǗ ȡȠ ÿƺǲǵ 10 ȡȠ ǰÀȠ Ž ŏÀȒĘ Ǵìǻ Ǧęǿş ÈÛ8ǩ :*Procedure* ǒäÄǱqǟ

.ǈȠ 40 × ǈȠ 15 ÈĘǑǩ ǦùÀïǗ Ž ȧǿƺöä ʒÛǑǻş ƵǲǬö ǒÀǬǩ .(ȯ/ȟ60~) ǬĘǬèɉä ȐƀȡȠ Æǵäş ǈǲǵş

.ǞÆĘǲ ǦǑŸ8Ƞ Ǧǻşǻǵ Ž î ÀòÀöä ğÀǬĘèǗ ȧǿş ȘÀƷ ȷǗ Ǣʑ :*Storage* ȡǻÂǾǬöä

Pb(NO$_3$)$_2$ ȡȠ ȟ 100 ʔŸʒ ɃƺǬƷ R î ÀòÀöä ğäÀǬÀö ȯƺŸƮ :TS (ȯ/ȟ100) (Lead nitrate) î ÀòÀöä ğäÀǬ

.ÀǬŸöä Ž

.(105 ǦɄÀÔöä Û1963 ÛSRIP) PbO$_2$:R (Lead (IV) oxide) (IV) î ÀòÀöä ǼĘÊǒşǗ

.ǦĘöşǻ ǦĘǝÀĘȶĘǒ ǦĘȞǱÀȠ gǻÀȠ :RS (Levonorgestrel) ǬÀÀǬÊĘǲǿƺǬƺÀĘŸöä

.ǦĘöşǻ ǦĘǝÀĘȶĘǒ ǦĘȞǱÀȠ gǻÀȠ :RS (Levothyroxine sodium) ƙÊǒşƘǬƺÀĘŸöä ÿƺÀǻƺò

.ǦĘöşǻ ǦĘǝÀĘȶĘǒ ǦĘȞǱÀȠ gǻÀȠ :RS (Liothyronine) ƙǬşƘǬƺĘŸöä

.Li$_2$CO$_3$:R (Lithium carbonate) ÿƺĘǯĘŸöä ğÀǬƺǟÀǒ

.ǦɄǝäÀöä ƇǼʒ ÜȒĘǟǗ ǢǤƮ ȧƺɄÊȠ :*Description* Ƶòƺöä

.TS (ȯ/ȟ750~) ȯƺǬÀǯÀqä Ž ǞǼǲ ȷÀǟşǾöä ǴĘɄì ÜǒÀȶä Ž ȷÀǟşǾöä ǬĘŸę :*Solubility* ǦĘǬÀǟşǾöä

:TS (Lithium carbonate/trinitrophenol) ȯƺǼƺşÀǬĘǬ ɄǬŸǬ/ÿƺĘǯĘŸöä ğÀǬƺǟÀǒ

ȡȠ ǦĘƺÀǒ ǦĘȶǒ Ž R ȯƺǼƺşÀǬĘǬ ɄǬŸǬ ȡȠ ȟ 0.5ş R ÿƺĘǯĘŸöä ğÀǬƺǟÀǒ ȡȠ ȟ 0.25 āäǾÀ :*Procedure* ǒäÄǱqǟ

.ǬȠ 100 ǯÀǬq ǒÀȶä

.LiCl :R (Lithium chloride) ÿƺĘǯĘŸöä ǼÀǿƺŸǒ

.ǒÀȒĘǟ ÛǦʒƺĘȠ ğäǿƺŸǟşǗ ğÀĢĘǵ :*Description* Ƶòƺöä

.R ƘǬɉäş ÛTS (ȯ/ȟ750~) ȯƺǬÀǯÀqä ÛR ȷƺǬĘèɉä Ž āäşǽ ÜǒÀȶä Ž ȷÀǟşǾöä Àǵ :*Solubility* ǦĘǬÀǟşǾöä

.ÿÀȮǵüǟ ǦǑŸ8Ƞ Ǧǻşǻǵ Ž ȷÂƩ :*Storage* ȡǻÂǾǬöä

Ž LiCl ȡȠ ȟ 10 ǦǟäÀę ʔŸʒ ɃƺǬƷ ÿƺĘǯĘŸöä ǼÀǿƺŸȮö ȯƺŸƮ :TS (ȯ/ȟ10) (Lithium chloride) ÿƺĘǯĘŸöä ǼÀǿƺŸǒ

.ÀǬŸöä

.ǦĘöşǻ ǦĘǝÀĘȶĘǒ ǦĘȞǱÀȠ gǻÀȠ :RS (Loperamide hydrochloride) ǼĘȠäƘǟƺŸöä ǼÀǿƺŸǒşǿǼĘȽ

:R (Macrogol 1000) 1000 ȯƺȡşÀǒÀȶä

.ǒÀȒĘǟ ǦĘȞɒ ǦŸǬǒ :*Description* Ƶòƺöä

.ǈȠ 17.3 m m^{2}s^{-1} ǦǟäÀę Û°ÿ 100 ǦǲǿǼöä Ž :*Viscosity* ǦǲşÂŸöä

p-tert- Û$C_{34}H_{62}O_{11}$ **:R (Macrogol *p*-isooctylphenyl ether)** ôzʠşÀõÅţä ÕÆÆz ÕÆÇõÛşÂÅÛ-***P*** ƘǭÛ
.octylphenoxy polyethoxy-ethanol

."Sterility testing of anibiotics ǦÅzÆΣä ğäåÅȒţä ǦŋÅÕ3 øÅǤǭǹä" ÕDZǂ ǦȶəѰŋ ǦDZøå ÿÆÁǭÊǩ

.$C_4H_6MgO_4,4H_2O$ **:R (Magnesium acetate)** ÿzÅlu8ţä ğÅǭÆèÜ

.Ǧ3zÆŋ ÛɈzÝöä ǦƩÆ3 ğäøzÝæ :*Description* *Ȥöȥöä*

.TS (ȯ/ȟ750~) ȯzǥÅǯÅqäş ÛöÅţä Ž ɈÅæşǾöä Àǵ :*Solubility* *ǦǯÅæşǾöä*

.(110 ǦǶÅÔöä Û1963 ÛSRIP) $MgCl_2,6H_2O$ **:R (Magnesium chloride)** ÿzÅlu8ţä ÆÅøzÝõ

:VS (ȯ/ȯzŋ 0.1) (Magnesium chloride) ÿzÅÂÆÅ8ţä ÆÅøzÝõ

.Õŋ 1000 ǯÅǭǥq ŏÅţä ȡŋ ǦÆzÅõ ǦÆȶõ Ž R ÿzÅlu8ţä ÆÅøzÝõ ȡŋ ȟ20.5 ǡäØÅ :*Procedure* *ǒäÄDZqä*

ǥÀÅÅȞţÅæ Ûȯ/ȯzŋ 0.1 ȯzÝǂ ȓzǤȒţä ÂÆõÀǭöä ȡŋ ǨǤǯǭöä ɃÀƶ :*Method of standardization* *ǥÄÅÅȞţä ǦÕÅÄü*
Õŋ Æǵäş Õõ .ÿzÅlu8ţä ÆÅøzÝõ ȯzÝȚ ȡŋ Õŋ 25 ÿäÆÁǭèÅæ (135 ǦǶÅÔöä Û1 ÆÝÕä) ÿzÅlu8ȶÝö ğäÆÕȞţä ǡäÆÕŋ
.$MgCl_2,6H_2O$ ȡŋ ȠÝŋ 20.33 üzÅÒÅ VS (ȯ/ȯzŋ 0.1) ÿzÅåzÔöä ğÅǭÅÆÅÜ ȡŋ

:TS (Mg Õŋ/ȠÝŋ 0.1) (Magnesium) ÿzÅlu8ţä
ȪÅøzÅÝÊöä Ȑþ ȡŋ Õŋ 5 8ÅȒÅ ÛöÅţÅæ R ÿzÅlu8ţä ğÅÅÝè ȡŋ ȟ 1.014 ǡäØÅ :*Procedure* *ǒäÄDZqä*
.ŏÅţÅæ Õŋ 1000 ƂÜ ȤÅƩş TS (ȯ/ȟ100~)

:TS (Mg Õŋ/ÿäÀʠşÀÒŋ 10) (Magnesium standard) ɃøÅÆȞţä ÿzÅlu8ţä
.Õŋ 100 ǯÅǭǥq ŏÅţä ȡŋ ǦÆzÅõ ǦÆȶÒæ TS (Õŋ/ȠÝŋ 0.1) ÿzÅlu8ţä ȡŋ Õŋ 10 ȤÅƩ

:TS (Magnesium sulfate/sulfuric acid) ȪÅøzÅÝÊöä Ȑþ/ÿzÅlu8ţä ğÅÅÝè
TS (ȯ/ȟ100~) ȪÅøzÅÝÊöä Ȑþ ȡŋ ǦÆzÅõ ǦÆȶõ Ž R ÿzÅlu8ţä ğÅÅÝè ȡŋ ȟ 25 ǡäØÅ :*Procedure* *ǒäÄDZqä*
.Õŋ 100 ǯÅǭǥq

.ǦÆöşå ǦÆəÅÆȶÆõ ǦÆȞDZÀŋ ǥåÅŋ **:RS (Mebendazole)** ȯşàäÆÅǤÆţä

.$C_{11}H_8O_2$ ÛɈzÆõzǯzÅǥ-4.1-ÕÆǯÆŋ-2 **:R (Menadione)** ɈzÅåÅÅÆţä

.ǦȞüÅè ŏäÀÅò ğäøzÝæ :*Description* *Ȥöȥöä*

.ȞǤÅÀÕǩ °ÿ 106 :*Melting temperature* *øÅȚÔǥȓä ǦDZøå*

:TS (Mercuric chloride/ethanol) ȯzǥÅǯÅqä/ȪÆÕǤəÂöä ÆÅøzÝõ
ǯÅǭǥq TS (ȯ/ȟ375~) ȯzǥÅǯÅqä ȡŋ ǦÆzÅõ ǦÆȶõ Ž R ȪÆÕǤəÂöä ÆÅøzÝè ȡŋ ȟ 2 ǡäØÅ :*Procedure* *ǒäÄDZqä*

.Ōŋ 100

:**TS (Mercuric nitrate)** ǑĒŎǤəÂöä ğäÀǫ

ǑǺÄǫǺöä Ȑþ ȸŋ Ōŋ 32 ȸŋ ǰǺÂŋ Ž R ÀÀòɉä ǑĒŎǤəÂöä ǼĒÊõǖ ȸŋ ȟ 40 ā äǾǺ :*Procedure ǒäÄǱǭä*
.ǒǺţä ȸŋ Ōŋ 15ş TS (ȯ/ȟ1000~)

.ǒȥȒöä ȸŋ ǦĒȶŢ ǦǺşǺǵ Ž ȼŢǺǵ Ǣƶ :*Storage ȸǺÂǺǾöä*

:**VS** (ȯ/ȯȥŋ **0.02**) **(Mercuric nitrate)** ǑĒŎǤəÂöä ğäÀǫ

Ȑþ ȸŋ Ōŋ 10 ȸŋ ǰǺÂŋ Ž ā äǾǩ ÛR ǑĒŎǤəÂöä ğäÀǫ ȸŋ ȟ 6.85 ǦääÀę ǦĒüȥǤȒŋ ȷàȥǺ :*Procedure ǒäÄǱǭä*
.Ōŋ 1000 ʔøǫǵ ǒǺţǺ Ȥ ǺƩş ÛǒǺţä ȸŋ Ōŋ 500ş TS (ȯ/ȟ130~) ǑǺÀǫǺöä

ţǺǦǨǺ ȯ/ȯȥŋ 0.02 ȯȥŸǂ ȓȥǤȒţä ǺĒõÀǫöä ȸŋ ǨǦǯǫöä ɃÀƶ :*Method of standardization ǥÄǺǶţä ǦŎǺÀü*
.190 ǦĦǺÔöä Û1 ǼŸŎä VS (ȯ/ȯȥŋ 0.01) ǑĒŎǤəÂöä ğäÀǫ ȷäȥǺȝ ǨƠ Ǧȥȥòȥţä ǦŎǺÀÛöä

:**TS (Mercury/nitric acid)** ǑǺÀǫǺöä Ȑþ/ĘǤəÂöä

ǈǱƜ ȯȥŸǂä Ȥ ǺƩş R ǻøǺǤöä ÀǺǤţä ǑǺÀǫǺöä Ȑþ ȸŋ Ōŋ 27 Ž R ĘǤəÂöä ȸŋ Ōŋ 3 ā äǾǺ :*Procedure ǒäÄǱǭä*
.ǒǺţä ȸŋ ȯǻǺĦŋ

.ȸǺÀȚÎöä àşǺǱǫǨ ɟ ǥǼŋ Ž ÛǒȥȒöä ȸŋ ǺĒȶŢ ȯȥŸǂä ȷÂƩ ȷǖ Ǣƶ :*Storage ȸǺÂǺǾöä*

.ǦĒşǻ ǦĒĦǱÀŋ ǦĒəǺĒȶĒõ ǥǻǺŋ :**RS (Methotrexate)** ğǺÊȮǺÀǩȥǯĒţä

.ǦĒşǻ ǦĒĦǱÀŋ ǦĒəǺĒȶĒõ ǥǻǺŋ :**RS (Metoclopramide hydrochloride)** ǼĒŋäÀǼȥŸõȥǫĒŋ ǼǺǿȥŸõşǿǼĒȽ

.ǦĒşǻ ǦĒĦǱÀŋ ǦĒəǺĒȶĒõ ǥǻǺŋ :**RS (Miconazole nitrate)** ȯşàǺǫȥȮĒţä ğäÀǫ

.(120 ǦĦǺÔöä Û1963 ÛSRIP) MoO_3 :**R (Molybdenum trioxide)** ÿȥǺǺǼǤöȥţä ǼĒÊõǖ ɄǫŶǫ

.C_2H_7NO :**R (Monoethanolamine)** ƙŋɟȥǫǺǯǺǖ ɃǻǺǵǖ

.ǦǺǿǻǺÎǫ ȼǫĦəäǿ Üȣǻò ÛȷȥŸöä ȻǼȝ şǖ ǨȽǺǼ ÀǺòǖ ÛȝǺö ŎəǺè :*Description Ȥòȥöä*

.R ȷȥǫĒèɉäş R ȯȥǫǺǯĒţäş ǒǺţǺ ȝǺȶŸö ŎǼǺę :*Miscibility ǦĒǱşǺţä*

.ǺǤǺÀŎǩ °ÿ 170 :*Boiling temperature ȷǺĒȣöä ǦǱǿǺ*

.$\rho_{20} = $ ȯ/ŋõ 1.01 :*Mass density ǦŶǫȮöä ǦȥǺǯõ*

. $n_{\mathrm{D}}^{20} = 1.453 - 1.455$:*Refractive index ǿǺÊȮǫɟǺ ǢÊǺŋ*

.ǦĒşǻ ǦĒĦǱÀŋ ǦĒəǺĒȶĒõ ǥǻǺŋ :**RS (Naloxone hydrochloride)** ȷȥÊȮǒǺǺöä ǼǺǿȥŸõşǿǼĒȽ

.ǦĒşǻ ǦĒĦǱÀŋ ǦĒəǺĒȶĒõ ǥǻǺŋ :**RS (Neamine)** ƙŋǺǼǺöä

:RS (Neomycin B sulfate) B

RS (Framycetin sulfate) *INN* :

:RS (Neostigmine metilsulfate)

.(124 1963 SRIP) $C_{15}H_{17}ClN_4$ C.I. C.I. 50040 :R (Neutral red)

:TS (Neutral red/ethanol)

100 TS (~375) R 0.1 :*Procedure*

:RS (Nifurtimox)

:RS (Niridazole)

:RS (Niridazole-chlorethylcarboxamide)

:RS (Nitrofurantion)

.CH_3NO_2 :R (Nitromethane)

:*Description*

.R TS (~750) :*Miscibility*

ρ_{20} = 1.13 :*(Mass density)*

$n_D^{20} = 1.380$:*Refractive index*

101 °:*(Boiling temperature)*

:RS (Noscapine)

:RS (Nystatin)

.$C_8H_{16}O_2$:R (Octanoic acid)

:*Description*

237 °:*(Boiling temperature)*

0.92= ρ_{20} :*(Mass density)*

-4- -1 19 :R (Oracet blue B) B

.($C_{20}H_{14}N_2O_2$) ƙÆŏäÀǯĘфǖζÆŸĘфǗ-4-ζÆŋǗ-1ş ($C_{21}H_{16}N_2O_2$)

:TS (Oracet blue B/acetic acid) ÕĘϘèɟä Ȑþ/**B** ǨĘèäǿşɟä Ǥęǿà

R1 ɄDzŸǯöä ÕĘϘèɟä Ȑþ ȸŋ ǴĘζÀõ ǴĘŧõ Ž R B ǨĘèäǿşɟä Ǥęǿà ȸŋ ȟ 0.5 āäØÅ :*Procedure ǿǎÀDZqä*

.Ōŋ 100 ǯÀϘфq

.(131 ǴĦÀÔöä Û1963 ÛSRIP) $C_2H_2O_4,2H_2O$ **:R (Oxalic acid)** ÕĘöÀÊõşɟä Ȑþ

ȸŋ ȟ 0.05 ɁŸȝ ɃζϘƷ R ÕĘöÀÊõşɟä ȐŧΣ ȯζŸŢ **:TS** (ȯ/ȟ**0.05**) **(Oxalic acid)** ÕĘöÀÊõşɟä Ȑþ

.Ōŋ 1000 Ž $C_2H_2O_4$

.Ōŋ 1000 ǯÀϘфq ǒÀţä ȸŋ ǴĘζÀõ ǴĘŧõ Ž R ÕĘöÀÊõşɟä Ȑþ ȸŋ ȟ 0.07 āäØÅ :*Procedure ǿǎÀDZqä*

.ǴĘöşǻ ǴĘəÀĘŧĘõ ǴĘȞDZÀŋ ǥǻÀŋ **:RS (Oxamniquine)** ƙȮĘÅŋÀÊõşɟä

.ǴĘöşǻ ǴĘəÀĘŧĘõ ǴĘȞDZÀŋ ǥǻÀŋ **:RS (Oxytetracycline dihydrate)** ƙŸȮĘèäÀϘǩ ɄÊõşɟä ǧäǿÆĿ ɄəÀÅϘ

Ž ƸòşÀŧõ ȯζŋÀϘĘèäǿÀǤöä **:R (Paracetamol,4-aminophenol-free)** Àǵ-ȯζÆζζÆŋǗ-4 Ûȯζŋ ÀϘĘèäǿÀǤöä

:БÀϘöä ǿÀǤϘňŸö ÆĘDzϘÊÅ ɁøϘǵ ǒÀţä ȸŋ ȼǩǿζŸæ ǻÀȞţä ȯζŋÀϘĘèäǿÀǤöä şǗ Û237 ǴĦÀÔöä ÛǴòÀʅä ǥǻşÀζɟä

ǰÅÂţä äØŏ Ōŋ 100 ɁøϘǵ ƸÀƸş ǒÀţäş R ȯζфÀǯţä ȸŋ ӯζDzΣä ȯǻÀȞϘŋ ǰÅÂŋ Ž ǤζÀƨä ǥǻÀţä ȸŋ ȟ 5 āäØÅ

ɈζöǰϘÅÅ ғ ÜǴŌĘęǻ 30 ǥÆŋ ÀŐϘÊĘö ÕÀϘÅş ÛǯÂƩ ÛTS ɃζŸÕöä ӯζÅǻζÔöä ÆĘèşÀæşÀϘф Ōŋ 1.0 ȣÀȒÅ .ÆÅØţä

.ÀȒňǗ şǗ ȧǿàǗ

.$(CH_2O)_n$ **:R (Paraformaldehyde)** ÆĘĿÆöÀŋǿζζäǿÀæ

.ÆĘĿÆöÀŋǿζÀŸö ǥÂĘư ǴĦəäÀöä ÜȐĘæǗ Ƀǿζ Ÿæ ȧζĦÊŋ :*Description ƸòζǞä*

ÜÆĘĿÆöÀŋǿζÀöä evolution ƘƬṬǩ ȝŋ ÛǿÀΣä ǒÀţä Ž ɈÀæşØöä Àǵ ÛǻǿÀǤöä ǒÀţä Ž ǒÙǤæ āäşæ :*Solubility ǴĘфÀæşØöä*

.R ƘϘɟäş TS (ȯ/ȟ750~) ȯζфÀǯÅqä Ž ÀĘŸŧȝ āäşæ Ƙɖ

ȯζŸŢ ǰϘÅÅ ÜTS (ȯ/ȟ100~) ÀĘфζŋɟä ȸŋ Ōŋ 10 Ž ȟ 1 āäØÅ :*Solubility in ammonia* ÀĘфζŋɟä Ž ǴĘфÀæşØöä

.ɈζŸöä ƇÆȝş ÀĘŸŧȝ ȣÀò

.ȟ/ŋŸŋ 1.0 ȸȝ ÆÅÂÅ ғ :*Sulfated ash ǨÀŸÊţä ǻÀŋÀöä*

ǴǵÀɩÀöä ɈζȮǩ ÜǴɩÀÅş ǥÆǵäş ǴŌĘęǻ ǥÆŋ ǒÀŋ Ōŋ 20 ȝŋ ȟ 1 ǯÀÅ :*Acidity or alkalinity ǴÅζŸŌöä ȏζŧΣä*

.ÈŧÎöä ǻÀǤȝ ȧǿζö (ǴÅǻÀĘǵ) ǴöǻÀȞϘŋ

.ǴĘöşǻ ǴĘəÀĘŧĘõ ǴĘȞDZÀŋ ǥǻÀŋ **:RS (Paromomycin sulfate)** ƙÊĘŋζŋǿÀǤöä ǧÀŸè

.$C_5H_{11}NaO_3S,H_2O$:**R (1-Pentanesulfonic acid sodium salt)** Ȭ‍ǻǿʐ‍ȦŸѐ ɹ‍ȦǪȦǣ-**1** Ȑƥ ӯʐǻắʐὸ ǴŸɳ

.Ȑ‍ǣǕ Ƀǿʐ‍Ÿǣ ȧʐȞȆɳ :*Description* *Ζὸʐǖ*

.ǒ‍ȦƫǤ Ž ǡǣȘǣ :*Solubility* *ǴǣǷǣȘØǖ*

.ɹʐŸǖǡ ȻǼȝȘ ǖǣʐȦὸ ǒ‍ȦƫǤ ȸɳ Ȭɳ 25 Ž ȟ 1 ȯʐŸȚ ɹʐȮǻ :*Clarity and colour of solution* *ȯʐŸǂǣ ɹʐǒȘ ǒǻȦȎǖ*

.ȟ/ɳŸɳ 20 ȸɳ ȦǯȭǕ ɹʐȮǻ ɍ ǕȦȊǣʐ ȯǿȦȭ ǴȬǻȦȖǣ ƙȞǻ :*Water* *ǒ‍Ȧƫǣ*

:**(1-Pentanesulfonic acid)** Ȭ‍ǻǿʐ‍ȦŸѐ ɹ‍ȦǪȦǣ Ȑƥ-**1**

Ȑƥ ȸɳ Ȭɳ 1000 Ž R Ȭ‍ǻǿʐ‍ȦŸѐ ɹ‍ȦǪȦǣ-1 Ȑƥ ӯʐǻắʐὸ ǴŸɳ ȸɳ ȟ 0.960 ǡǣØǻ :*Procedure* *ǒǣȦDZɋǣ*

ǴȋȦǻ .TS (ȯ/ȟ260~) ȦǣǪʐɳɟȦǣ 4.3 ʔøǪǵ ǒ‍ȦȽȦǴǖǡ ʔʐȆǻȘ TS (ȯ/ȟ5.0) ǒǣʐTǣ ƫȘȂøȦƫǣ ȬǣǪǣѐɟǡ

.ȯȦȶȞǪѐɍǣ ȬǴȩ ǒǣʐTǣ ƫȂøȦȘ

:VS (ȯ/ȯʐɳ **0.1**) **(Perchloric acid/dioxan)** ɹ‍ȦȆȭʐǻǼǖǡ/Ȭ‍ǻǿʐŸȭƘǴǖǡ Ȑƥ

R ɹ‍ȦȆȭʐǻắ ȸɳ ǴǣʐȦȭ ǴǣȶȭʒɳTS (ȯ/ȟ1170~) Ȭ‍ǻǿʐŸȭƘǴǖǡ Ȑƥ ȸɳ ȯʐɳ 8.5 ʓȂɛ :*Procedure* *ǒǣȦDZɋǣ*

.Ȭɳ 1000 ʓȦǪǫɋ ȖǡǡȦǪɳɍȦǣ ǣȬǣȎǹ ʔȬȦƫǣ

ǧɍȦǯʐ ȸɳ ȟ 0.7 ǵȦǻȦȞɳ ȯʐŸǂ ȓʐǴȐƫǣ ȦǣȭȦǪǖǡ ȸɳ ǨǣǯǪǖǡ ɃȦʑ :*Method of standardization* *ǵȦȦȞƫǣ ǴȬǻȦǜ*

Ȧȶȭ ȖA ǴȬǻȦȖǖǡ ӯǣǼȂǪѐȦǣ ȖǴʒȦѐ 2 ǵǼɳ °ӯ120 ǴDZǿǼǣ ǣȬǣȦѐ ǴȦȦƒȘ ȖǴǣǜʐǴȐɳ ǴǪȘǡʐɳ ȖR ӯǣѐȦǩʐǴǖǡ ƙDZȘǿǼǣȽ

Ȭɳ 1 Ȭȭ .(142 ǴȞȦȎǖǡ Ȗ1 ǼŸȬǡ) "Non-aqueous titration ȚǝȦɳŸǖǡ Ǖѐʐǖǡ Ž ǵȦǻȦȞƫǣ" ɹǡʐǻʒ ǨƠ ȣʐὸʐɳ ʐȽ

.$C_8H_5KO_4$ ȸɳ ɳŸɳ 20.42 ǜʐȦȮǻ VS (ȯ/ȯʐɳ 0.1) ɹ‍ȦȆȭʐǻǼǖǡ/Ȭ‍ǻǿʐŸȭƘǴǖǡ Ȑƥ ȸɳ

:VS (ȯ/ȯʐɳ **0.02**) **(Perchloric acid)** Ȭ‍ǻǿʐŸȭƘǴǖǡ Ȑƥ

Ȑƥ ȸɳ ǴǣʐȦȭ ǴǣȶȭʒɳVS (ȯ/ȯʐɳ 0.1) Ȭ‍ǻǿʐŸȭƘǴǖǡ Ȑƥ ȸɳ Ȭɳ 20 ǡǣØǻ :*Procedure* *ǒǣȦDZɋǣ*

.Ȭɳ 100 ʓȦǪǫɋ R1 ȚDZŸǯǖǡ ȬǣǪǣѐɟǡ

ɃȦʑȘ ǒ‍Ȧƫǣ ʔʐǪȚ ǵȦȉȦǴɳ ӯǣǼȂǪѐɍǣ ȬǴȩ ƙȞǻ :*Water and method of standardization* *ǵȦȦȞƫǣ ǴȬǻȦǜȘ ǒ‍Ȧƫǣ*

ȖVS (ȯ/ȯʐɳ 0.1) Ȭ‍ǻǿʐŸȭƘǴǖǡ Ȑƥ ɹǡʐǻʒ ǨƠ Ǵʐʐὸʐƫǣ ǴȬǻȦȖǖǡ ƫȦǴȦǣ ȯʐŸȞȶŸȭ ȓʐǴȐƫǣ ȦǣȭȦǪǖǡ ȸɳ ǨǣǯǪǖǡ

.213 ǴȞȦȎǖǡ Ȗ1 ǼŸȬǡ

.$C_6H_8N_2,2HCl$:**R (1,4-Phenylenediamine dihydrochloride)** ƙɳȦǻắ ƙŸǣǼʐ-**4**Ȗ**1** ǼǻǿʐŸȭȘǿǼǣȽ ȚǝȦǪ

ɃǕ ȜŸȬǻ ȖȜǵȦȉ (ȄȶȊǖȦǣ ǼŸƨǣǿǖȦƧǣ ɹʐǒ) tan ʒȦȆȭǪɳ ɃǕ Ȑǣǖ Ƀǿʐ‍Ÿǣ ȧʐȞȆɳ :*Description* *Ζὸʐǖ*

.ǒǣʐŦŸ ȏ ȦȞǪǖǡ Ǽǻʒ ȚŸȦǫȦȩ

.R ƘǪɟǣȘ TS (ȯ/ȟ750~) ȯʐǫȦǯǻɋǣ Ž ɹ‍ȦǣȘØǖǡ ǴǣȞȉ ǕȯȦƫǣ Ž ɹ‍ȦǣȘØǖǡ Ȧǵ :*Solubility* *ǴǣǷǣȘØǖ*

.ǒʐȐǖǡ ȸɳ ʔȶʒ ɹǕȘ ȖǣǼǣDZ ǴȬŸȣɳ ǴǻȘȦǵ Ž ȘȦʒ :*Storage* *ȸȦȂǼǪǖ*

[illegible] **:TS (Phenylhydrazine/hydrochloric acid)**

Procedure: [illegible] 0.75 [illegible] 50 [illegible] 2 [illegible] 25 [illegible] TS (~420) [illegible] 200 [illegible].

[illegible] **(Phenylhydrazine hydrochloride)** **TS: (10** [illegible] $C_6H_8N_2,HCl$ [illegible] 10 [illegible] 1000 [illegible].

[illegible] **R (Phenyl/methylpolysiloxane):** [illegible] 5 [illegible] 95 [illegible] 100 [illegible].

[illegible] **Phosphate buffer** [illegible] **7.4** **TS** :

Procedure: [illegible] 6.8 [illegible] 250 [illegible] 393.4 [illegible] (0.1) VS.

[illegible] **Phosphate buffer** [illegible] **7.6** **TS:**

Procedure: [illegible] 1.36 [illegible] 200 [illegible] 42.4 [illegible] (0.2) VS [illegible].

[illegible] **Phosphate buffer** [illegible] **8.0** **TS** :

Procedure: [illegible] 8.95 [illegible] 0.50 [illegible] 1000 [illegible].

دارئة الفوسفات العقيمة Phosphate buffer, sterile، باهاء 7.8، TS:

Procedure: [illegible] 6.8 [illegible] 45.2 [illegible] (1) VS [illegible] 1000 [illegible] 7.8 [illegible] TS (~1440) [illegible] TS (~110) [illegible] 20 [illegible] 120 [illegible].

[illegible] **Phosphate buffer,sterile** [illegible] **10.5** **TS1:**

Procedure: [illegible] 35.0 [illegible] 20 [illegible] (1) VS [illegible] 1000 [illegible] 10.5 [illegible] TS (1440) [illegible] TS (~110) [illegible] 20 [illegible] 120 [illegible].

:TS Û**6.0** ǒǺĿǺǟ Û**Phosphate/citrate buffer** ğǟÀǪǼÊǚǟ ǦəøǟǻƒğǺÀèɀǺǚǟ

Ǿǡ 35 8ǺȒǺ ÛǒǺǡ Ǿǡ 60 Ž R ÿɀǺǻɀÔǚǟ ɄəǺǪ ƙDZşøǼǼ ğǺÀèɀɀ ȸǡ ȟ4.52 āǟØǺ :*Procedure ǒǟÄDZqǟ*

.6.0 ƂǗ ȯɀŸǂǟ ǒǺĿǺǟ ǴɄÔǐ ǵøşÀȒǚǟ ǼǺȝş TS (ȯ/ȟ20) ÕǺÀǪǼÊǚǟ Ȑ ƥ ȸǡ

:**TS** (Ǿǡ/ÿǟÀdzşÀǾǡ **5**) **Phosphate standard** ɃøǺǼȞţǟ ğǺÀèɀǺǚǟ

ǯǺǪǫq ǒǺţǟ ȸǡ ǦǼɀǺõ ǦǼȶõ Ž R ÿɀǼèǺǩɀǦǚǟ ƙDZşøǼǼ ɄəǺǪ ğǺÀèɀɀ ȸǡ ȟ 0.716 āǟØǺ :*Procedure ǒǟÄDZqǟ*

.ǒǺţǺǟ Ǿǡ 100 ƂǗ ÿǟǼǺǪèɍǟ ǾǦȩ ǵÀǐǺǦǡ Ǿǡ 1 ƸǺƩ ÛǾǡ 1000

:**TS** (ȯ/ȟ**105~**) **Phosphoric acid** ÕǺøɀǺèɀǺǚǟ Ȑ ƥ

.ǒǺǡ ȟ885 ȝǡ TS (ȯ/ȟ1440~) ÕǺøɀǺèɀǺǚǟ Ȑ ƥ ȸǡ ǦǺÀÕǩ ȟ115 ǯÂɀ :*Procedure ǒǟÄDZqǟ*

:**TS Phosphotungstic acid** ÕǼǪÊ8ǫɀǩɀǺèɀǺǚǟ Ȑ ƥ

Ȑ ƥ ȸǡ Ǿǡ 18.75 8ǺȒǺş ǒǺţǟ ȸǡ Ǿǡ 75 Ž R ÿɀǺǻɀÔǚǟ ğǺǪÊ8ǫɀǩ ȸǡ ȟ 25 āǟØǺ :*Procedure ǒǟÄDZqǟ*

ǦǼȶõ 8ǺȒǺş ÛǴïÀǺ ÛğǺȝǺè 6 ǵǼǡ ɄȝɀDZø ȷǺÀɀǟ ǾȶȞǺ ƸǯǾǡ ǨƠ ȸǺÊǺ .TS (ȯ/ȟ1440~) ÕǺøɀǺèɀǺǚǟ

.Ǿǡ 250 ǯǺǪǫq ǒǺţǟ ȸǡ ǦǼɀǺõ

.ǒɀȒǚǟ ȸǡ ɁȶȜ Û°ÿ 8ş 2 ƙǟ dzşǟÀǪǩ ǵøǟÀǵ ǦDZøǼǟ ȷÂƩ :*Storage ȸǺÂǺǪǚǟ*

.$C_5H_{11}N$:**R (Piperidine)** ȸǺǼǺȜǼǦǚǟ

.ǵÂǼư ǴɄəǟÀǚǟ ÜÀǺÔǡ şǗ ȷɀŸǚǟ ǷǼȝ ǾəǺè :*Description Ƹöɀǚǟ*

.TS (ȯ/ȟ750~) ȯɀǫǺǯǺqǟş ǒǺţǺǟ ǯşÂǡ :*Miscibility ǦDZşÂţǟ*

.ǦǺÀÕǩ ρ_{20} = ȯ/ǹõ 0.86 :*Mass density ǦŸǪÔǚǟ ǦɀǺǯõ*

.ǦǺÀÕǩ $n_D^{20} = 1.454$:*Refractive index øǺÊÔǫɍǟ ǼÊǺǡ*

.ǦǺÀÕǩ °ÿ 106 :*Boiling temperature ȷǼŸ8ǚǟ ǵøǟÀǵ ǦDZøǻ*

.°ÿ 15ş 12 ƙǟ :*Congealing temperature ǻǺȶƠɍǟ ǦDZøǻ*

.(145 ǴɄǺÔǚǟ Û1963 ÛSRIP) $KSbO_3$:**R (Potassium antimonate)** ÿɀǼèǺǩɀǦǚǟ ğǺǫɀȶǪǗ

:**TS (Potassium antimonate)** ÿɀǼèǺǩɀǦǚǟ ğǺǫɀȶǪǗ

8ǺȒǺş ǼȞǺèǺ ǻȜǩ ÛȷǺǟşØǚǟ ȜøǪǵ ǒǺǡ Ǿǡ 95 Ž R ÿɀǼèǺǩɀǦǚǟ ğǺǫɀȶǪǗ ȸǡ ȟ 2 ȜŸ8Ǻ :*Procedure ǒǟÄDZqǟ*

õÀǪǺ .VS (ȯ/ȯɀǡ 1) ÿɀǺǻɀÔǚǟ ǼǼÊõşøǼǼ ȸǡ Ǿǡ 5ş VS (ȯ/ȯɀǡ 1) ÿɀǼèǺǩɀǦǚǟ ǼǼÊõşøǼǼ ȸǡ Ǿǡ 50

.Ǿǡ 150 ǯǺǪǫq ǒǺţǟ ȸǡ ǦǼɀǺõ ǦǼȶÔǟ ƸǺƩş ǦȝǺè 24 ǵǼǡ ÀÕǪÊǼǚ

ÜǾǡ 10 ƂǗ (ȯ/ȯɀǡ 0.1) ÿɀǺǻɀÔǚǟ ǼǼÊõşøǼǼ ȸǡ Ǿǡ 7 8ǺȒǺ :*Sensitivity to sodium ÿɀǺǻɀÔǚǟ ǦèǺÊƩǟ*

.ǦÕǼȩǻ 15 ȯŸǹ ǒǺȒǼǟ ǦǺøɀŸǟ ǦǟǺèɓ ǾȮÎǪǩ

[illegible] TS [illegible]: [illegible]

[illegible] **Potassium bromate** (0.00833 [illegible]) **VS**: [illegible]
[illegible] 1.392 [illegible] $KBrO_3$ [illegible] 1000 [illegible].

[illegible] **(Potassium carbonate) R**: $K_2CO_3,1_{1/2}H_2O$.

Description [illegible]: [illegible].

Solubility [illegible]: [illegible] (~750 [illegible]) TS.

[illegible] **(Potassium carbonate,anhydrous) R**: K_2CO_3.

Description [illegible]: [illegible].

Solubility [illegible]: [illegible] (~750 [illegible]) TS.

[illegible] **(Potassium chloride)** **(100 [illegible]) TS**: [illegible] R [illegible] 100
[illegible] KCl [illegible].

[illegible] **(Potassium cyanide) PbTS**:

Procedure [illegible]: 10 [illegible] R [illegible] 90 [illegible] 2 [illegible]
[illegible] (~60 [illegible]) TS [illegible] 24 [illegible] 100 [illegible].

[illegible] **(Potassium dichromate) TS2**:

Procedure [illegible]: 1 [illegible] R [illegible] 60 [illegible] 7.5 [illegible]
[illegible] (~1760 [illegible]) TS.

[illegible] **(Potassium dichromate) TS3**:

Procedure [illegible]: 0.5 [illegible] R [illegible]
(~100 [illegible]) TS [illegible] 100 [illegible].

[illegible] **(Potassium dihydrogen phosphate)** **(100 [illegible]) TS**: [illegible]
[illegible] R [illegible] 100 [illegible] KH_2PO_4 [illegible].

[illegible] **(Potassium dihydrogen phosphate)** **(27.2 [illegible]) TS**: [illegible]
[illegible] R [illegible] 27.2 [illegible] KH_2PO_4 [illegible] (0.2 [illegible]).

[illegible] **(Potassium dihydrogen phosphate)** **(13.6 [illegible]) TS**:
[illegible] R [illegible] 13.6 [illegible] KH_2PO_4 [illegible] (0.1 [illegible]).

ʔŸʒ Ƀʐǭʒ ÿʐĚèÅǩʐǤöä ğäåʐĚö ǞDZäÅù ÀȒʈ ȯʐŸʈ :TS (ȯ/ŊŸŋ 3.6) (Potassium iodate) ÿʐĚèÅǩʐǤöä ğäåʐʌ .ÄǪŸöä Ž KIO_3 ȸŋ ŊŸŋ 3.6

Ž KI ȸŋ ȟ 100 ǦäÅę Ƀʐǭʒ ÿʐĚèÅǩʐǤöä ÆʌåʐĚö ȯʐŸʈ :TS (ȯ/ȟ100) (Potassium iodide) ÿʐĚèÅǩʐǤöä Æʌåʐʌ .ÄǪŸöä

:TS2 (Potassium iodoplatinate) ÿʐĚèÅǩʐǤöä ğÅÆĚǩƳæş åʐʌ

Æʌåʐʌ ȸŋ Ōŋ 45 ȣÅȒʌ ÛöÅʈä ȸŋ Ōŋ 2.5 Ž R ŌĚÆǪʌƳǤöä ÆʌøʐŸõ ȸŋ ȟ 0.25 ãäØʌ :*Procedure õäÄDZqä*
.Ōŋ 100 ǯÅǪqq R Jʐǭèɉä ȸŋ ǦĚʐÅõ ǦĚʈÒæ ZÅƩş ÛTS (ȯ/ȟ100) ÿʐĚèÅǩʐǤöä

ʔŸʒ Ƀʐǭʒ ÿʐĚèÅǩʐǤöä ğÅφÅȣʌŋƘǤö ȯʐŸʈ :TS (ȯ/ȟ25) Potassium permanganate) ÿʐĚèÅǩʐǤöä ğÅφÅȣʌŋƘæ .ÄǪŸöä Ž $KMnO_4$ ȸŋ ȟ25

ʔŸʒ Ƀʐǭʒ R ÿʐĚèÅǩʐǤöä ğÅφÅĚèʐĚǯö ȯʐŸʈ :TS (ȯ/ȟ200) (Potassium thiocyanate) ÿʐĚèÅǩʐǤöä ğÅφÅĚèʐĚǭ .ÄǪŸöä Ž KCNS ȸŋ ȟ 200

.ǦĚöşå ǦĚəÅĚʈĚõ ǦĚȞDZÀŋ ğåÅŋ :RS (Praziquantel) ŌĚǪφäʐȮʌäãƎöä

.ǦĚöşå ǦĚəÅĚʈĚõ ǦĚȞDZÀŋ ğåÅŋ :RS (Prednisolone acetate) Jʐöş Âøʌʌå Ǝöä ğÅǪĚèǕ

.ǦĚöşå ǦĚəÅĚʈĚõ ǦĚȞDZÀŋ ğåÅŋ :RS (Prednisolone sodium phosphate) Jʐöş Âøʌʌå Ǝöä ÿʐʌåʐò ğÅÀèʐʐ

.ǦĚöşå ǦĚəÅĚʈĚõ ǦĚȞDZÀŋ ğåÅŋ :RS (Probenecid) ÆĚÊÅæşƎöä

.ǦĚöşå ǦĚəÅĚʈĚõ ǦĚȞDZÀŋ ğåÅŋ :RS (Procarbazine hydrochloride) ȸʌäÅæøÅõşƎöä ÆʌøʐŸõşøÆĚȽ

.ǦĚöşå ǦĚəÅĚʈĚõ ǦĚȞDZÀŋ ğåÅŋ :RS (Protionamide) ÆĚŋÅφʐǭʌşƎöä

.ǦĚöşå ǦĚəÅĚʈĚõ ǦĚȞDZÀŋ ğåÅŋ :RS (Pyrantel embonate) ŌĚǪφäƘǤöä ğÅφʐǤŋǕ

.ǦĚöşå ǦĚəÅĚʈĚõ ǦĚȞDZÀŋ ğåÅŋ :RS (Pyrazinamide) ÆĚŋÅÅʌäãƘǤöä

.ǦĚöşå ǦĚəÅĚʈĚõ ǦĚȞDZÀŋ ğåÅŋ :RS (Pyrimethamine) ƙŋÅǯĚƩƘǤöä

.ǦĚöşå ǦĚəÅĚʈĚõ ǦĚȞDZÀŋ ğåÅŋ :RS (Rifampicin quinone ƙÊĚǤŋÅÅʌÀöä JʐÆĚõ

.ǦĚöşå ǦĚəÅĚʈĚõ ǦĚȞDZÀŋ ğåÅŋ :RS (Rifampicin) ƙÊĚǤŋÅÅʌÀöä

.ǦĚöşå ǦĚəÅĚʈĚõ ǦĚȞDZÀŋ ğåÅŋ :RS (Salbutamol) ȯʐŋÅǩʐǤöÅÊöä

.ǦĚöşå ǦĚəÅĚʈĚõ ǦĚȞDZÀŋ ğåÅŋ :RS (Salbutamol sulfate) ȯʐŋÅǩʐǤöÅÊöä ğÅÅŸè

.$C_7H_6O_2$:R (Salicylaldehyde) ÆĚȽÆöƳĚÊöÅè

:*Description*

.R TS (~750) :*Solubility*

. $d_{D}^{20} = 1.17$: *Relative density*

:TS (Salicylaldehyde)

0.1 R 100 R 2 :*Procedure*

.TS (~420)

.(UV 254) 60 **:R6 (Silica gel)**

:*Description*

6 :*Average pore size*

15 :*Composition*

.(15) 254

:TS(100) Silver nitrate

.1000 $AgNO_3$ 100

:VS(0.01) Silver nitrate

.$AgNO_3$ 1.699

:*Method of standardization*

.202 1 VS (0.1)

:TS (Silver nitrate/methanol)

.R R :*Procedure*

:VS (0.1) (Sodium acetate/glacial acetic acid)

100 R 5.3 :*Procedure*

R1 R1

.1000

:*Method of standardization*

3-2 VS (0.1) 15.0

8.203 VS (0.1) 1 .TS

.$C_2H_3NaO_2$

:**TS** (ὀ/ȟ**10**) **(Sodium alizarinsulfonate)** ӯζ⅄ǻζÔӧӓ ğǺφζÀŸѐ ȸ⅄øӓÂǢӧŬ

.ÀϘŸӧӓ Ž $C_{14}H_7NaO_7S$ ȸɳ ȟ 10 ǦӕӓÀȩ ɁŸȝ ɃζϘƷ ӯζ⅄ǻζÔӧӓ ğǺφζÀŸѐ ȸ⅄øӓÂǢӧȼ ὀζŸȚ

:**TS** (ὀ/ȟ**400**) **Sodium choride** ӯζ⅄ǻζÔӧӓ Ǽ⅄øζŸõ

.ÀϘŸӧӓ Ž NaCl ȸɳ ȟ 400 ǦӕӓÀȩ ɁŸȝ ɃζϘƷ ӯζ⅄ǻζÔӧӓ Ǽ⅄øζŸõ ȸɳ ȜÎɳ ὀζŸȚ

:**TS** (ὀ/ȟ**10**) **Sodium choride** ӯζ⅄ǻζÔӧӓ Ǽ⅄øζŸõ

.ÀϘŸӧӓ Ž NaCl ȸɳ ȟ10 ǦӕӓÀȩ ɁŸȝ ɃζϘƷ ӯζ⅄ǻζÔӧӓ Ǽ⅄øζŸÒӧ ὀζŸȚ

.ǦǢӧȿǻ ǦǢəÀǢȶǢõ ǦǢȞǱZÀɳ ğǻÀɳ :**RS (Sodium cromoglicate)** ӯζ⅄ǻζÔӧӓ ğÀÒǢŸȡζɳȿÀõ

ğÀÀѐζζ ὀζŸȚ :**TS** (ὀ/ȟ **275**) **(Sodium dihydrogen phosphate)** ӯζ⅄ǻζÔӧӓ ƙǱȿøǼǢȽ ƱəÀÀϘ ğÀÀѐζζ

.ÀϘŸӧӓ Ž NaH_2PO_4 ȸɳ ȟ 275 ǦӕӓÀȩ ɁŸȝ ɃζϘƷ ӯζ⅄ǻζÔӧӓ ƙǱȿøǼǢȽ ƱəÀÀϘ

.$CHNaO_2$:**R (Sodium formate)** ӯζ⅄ǻζÔӧӓ ğÀɳøζζ

.ǦÀǢÀǹ ÕǢɳøζζ ȒƥǦƱəӓø ȼӧ Ůȶζɳ ŮȒǢӓŮ ɃøζŸӕ ȿŮ ǼǤȚ ȧζƱÊɳ :*Description* *Ƶὂζӧӓ*

.°ӯ 253 :*Melting temperature* *øÀŢÔφɍӓ ǦǱZøǻ*

:**TS(Sodium hydroxide/ethanol)** ὀζφÀƷ⅄qӓ/ӯζ⅄ǻζÔӧӓ ǼǢÊõȿøǼǢȽ

TS (ὀ/ȟ750~) ὀζφÀƷ⅄qӓ ȸɳ ǦǢζÀõ ǦǢȶõ Ž R ӯζ⅄ǻζÔӧӓ ǼǢÊõȿøǼǢȽ ȸɳ ȟ 50 āӓØ⅄ :*Procedure* *ὂӓÀǱZqӓ*

.Ōɳ 1000 ȜÀϘφq

:**TS** (ὀ/ȟ**50**) **Sodium hydroxide** ӯζ⅄ǻζÔӧӓ ǼǢÊõȿøǼǢȽ

.ÀϘŸӧӓ Ž NaOH ȸɳ ȟ50 ǦӕӓÀȩ ɁŸȝ ɃζϘƷ ӯζ⅄ǻζÔӧӓ ǼǢÊõȿøǼǢŢ ὀζŸȚ

:**TS** (ὀ/ȟ**35**) **Sodium nitrite** ӯζ⅄ǻζÔӧӓ Ǩ⅄ÀϘφ

.(ǨǤ⅄ÀŌǩ ὀζɳ 0.5) ÀϘŸӧӓ Ž $NaNO_2$ ȸɳ ȟ35 ǦӕӓÀȩ ɁŸȝ ɃζϘƷ R ӯζ⅄ǻζÔӧӓ Ǩ⅄ÀϘ⅄ӧ ὀζŸȚ

ɁŸȝ ɃζϘƷ R ӯζ⅄ǻζÔӧӓ ǼǢѐȿÀӕȿÀϘ⅄ӧ ὀζŸȚ :**TS** (ὀ/ȟ**8.5**) **Sodium Nitroprusside** ӯζ⅄ǻζÔӧӓ ǼǢѐȿÀӕȿÀϘφ

.ÀϘŸӧӓ Ž $Na_2Fe(NO)(CN)_5$ ȸɳ ȟ 8.5 ǦӕӓÀȩ

:**TS (Sodium Nitroprusside, alkaline)** ɃζŸŌӧӓ ӯζ⅄ǻζÔӧӓ ǼǢѐȿÀӕȿÀϘφ

ǦǢζÀõ ǦǢȶõ Ž R ӯζ⅄ǻζÔӧӓ ğÀφζӕÀõ ȸɳ ȟ 1ȿ R ӯζ⅄ǻζÔӧӓ ǼǢѐȿÀӕȿÀϘφ ȸɳ ȟ 1 āӓØ⅄ :*Procedure* *ὂӓÀǱZqӓ*

.Ōɳ 100 ȜÀϘφq ὂÀȶӓ ȸɳ

.(191ǦƱÀÔӧӓ Û1963 ÛSRIP) Na_2O_2 :**Sodium peroxide** ӯζ⅄ǻζÔӧӓ ǼǢÊõȿǨӕ

Ȣζὂζɳ ζȽ Àȶõ ӯζ⅄ǻζÔӧӓ ğŸǢÊǢӧÀѐ ӯǼÅϘÊǩ .$C_7H_5NaO_3$:**R** (**Sodium salicylate**) ӯζ⅄ǻζÔӧӓ ğŸǢÊǢӧÀѐ

.217 ǦƠǺÔǻǻ Û2 ǼŸǑǻ Ž gǻşǺʐɉǻ Ž

11.5 ʔŸ3 ɃʐǪƷ R ÿʐǺǻʐÔǻǻ ğŸǺÊǺǻǺÊǻ ȯʐŸȚ :**TS** (ȯ/ȟ **11.5**) **Sodium salicylate** ÿʐǺǻʐÔǻǻ ğŸǺÊǺǻǺè

.ǺǪŸǻ Ž $C_7H_5NaO_3$ ȸȠ ȟ

.(196 ǦƠǺÔǻǻ Û1963 ÛSRIP) $Na_2SO_3,7H_2O$:**TS (Sodium sulfite)** ÿʐǺǻʐÔǻǻ ǨǺǺŸè

.ǦǺǻşǻ ǦǺǻǺƭǺÕ ǦǺǺDZǺȠ gǻǺȠ :**RS (Spectinomycin hydrochloide)** ƙÊǺǺȠʐǪǺȮǦÊǻǻ ǼǺǿʐŸÕşǿǼǺȽ

.ǦǺǻşǻ ǦǺǻǺƭǺÕ ǦǺǺDZǺȠ gǻǺȠ :**RS (Spironolactone)** ȷʐǪÕɍʐǫşƘǦÊǻǻ

.$C_{30}H_{62}$ ÜȷǻǻʐÕǻǺǪǩ ǑǺǮǺȠ ɄèǻǼè-23Û19Û15Û10Û6Û2 :**R(Squalane)** ȷɍǻʐȮÊǻǻ

.ȷʐŸǻǻ ǇǼȝ ɄøǪǻ ǑǻǺè :*Description* *ʐöʐǻǻ*

ȯʐǫǺǮǺɋǻş R ȷʐǪèɉǻ Ž ȷǺǻşǾǻǻ ǴǺƠì ÜR ÿʐʐşǿʐŸȮǻǻş R ƘǪɉǻ Ž ȷǺǻşǾǻǻ Ǻǵ :*Solubility* *ǦǺǫǺǻşǾǻǻ*

.TS (ȯ/ȟ750~)

. $d_{20}^{20} = 0.811 - 0.813$:*Relative density* *ǦǺǦÊǺǻǻ ǦʐǺǮȮǻǻ*

. $n_D^{20} = 1.451 - 1.453$: Refractiv index*ǿǺÊȮǫɍǻ ǼÊǺȠ*

:**R (Sudan red)** ȷǻǻʐÊǻǻ gǺƥ

.$C_{22}H_{16}N_4O$ ÜC.I. 26100 Ü23 ǼǺǾƫǻ gǺƥ ÜIII ȷǻǻʐè ÜȯʐǪʐǺǫ-2-(şǻŸǺǺʐşǻŸǺǺʐ-4)-1

.ǺƭȚ Ʉøǻǻ ȧʐƠÊȠ :*Description* *ʐöʐǻǻ*

.R ÿʐʐşǿʐŸȮǻǻ Ž ǡǻşǽ ÜǒǺƫǻ Ž ǡǻşǽ Ƙȡ ǺǺŸƭȝ :*Solubility* *ǦǺǫǺǻşǾǻǻ*

:**TS (Sudan red)** ȷǻǻʐÊǻǻ gǺƥ

.R1 ɄDZŸǮǻǻ ȪǺǪèɉǻ Ȑƥ ȸȠ 100 Ž R G ȷǻǻʐÊǻǻ gǺƥ ȸȠ ȟ 0.5 ǡǻǾǺ :*Procedure* *ǿǻǺDZɋǻ*

.ǦǺǻşǻ ǦǺǻǺƭǺÕ ǦǺǺDZǺȠ gǻǺȠ :**RS (Sulfacetamide)** ǼǺȠǺǪèǺǺŸÊǻǻ

.ǦǺǻşǻ ǦǺǻǺƭǺÕ ǦǺǺDZǺȠ gǻǺȠ :**RS (Sulfadimidine)** ȷşǼǺƩǺǺŸÊǻǻ

.ǦǺǻşǻ ǦǺǻǺƭǺÕ ǦǺǺDZǺȠ gǻǺȠ :**RS (Sulfadoxine)** ƙÊÕşǻǺǺŸÊǻǻ

H_3NO_3S ȸȠ ȟ5 ǦǻǻǺȩ ʔŸ3 ɃʐǪƷ R ȪǺȠǺǺŸÊǻǻ Ȑƭ∑ ȯʐŸȚ :**TS** (ȯ/ȟ5) **(Sulfamic acid)** ȪǺȠǺǺŸÊǻǻ Ȑƥ

.ǺǪŸǻ Ž

:**TS (Sulfanilic acid, diazotized)** ǺǺǼƫǻ ȪǺŸǺǫǺǺŸÊǻǻ Ȑƥ

VS (ȯ/ȯʐȠ 1) ȪǺǿʐŸÕşǿǼǺȚǻ Ȑƥ ȸȠ ǑȠ 20 Ž ȪǺŸǺǫǺǺŸÊǻǻ Ȑƥ ȸȠ ȟ 0.2 ǡǻǾǺ :*Procedure* *ǿǻǺDZɋǻ*

(ȯ/ȟ35) ÿʐǺǻʐÔǻǻ ǨǺǺǪǫ ȸȠ ǑȠ 2.5 ǺƭǪÊƫǻ ȪǺǺƠǪǻ 3Ƞ gǺÛȩ ǺǪǕ gǺÛȩ ȣǺȒǺ ÛǼǺŸƨǻ Ž ǻƎǺ ÛƙǺÊǪǻ 3Ƞ

[illegible] 1 [illegible] 10 [illegible] TS (50 [illegible]).

[illegible] **RS (Sulfasalazine)**: [illegible].

[illegible] **TS (Sulfuric acid/methanol)**:

Procedure [illegible]: [illegible] 10 [illegible] TS (~1760 [illegible]) [illegible] 90 [illegible] R.

[illegible]

[illegible] **(Sulfuric acid)** [illegible] (**0.125** [illegible]) **VS**: [illegible] TS (~1760 [illegible]) [illegible]

[illegible] 12.52 [illegible] H_2SO_4 [illegible] 1000 [illegible].

Method of standardization [illegible]

[illegible] VS (0.5 [illegible]) [illegible] 1 [illegible] 209.

[illegible] **R (Tannic acid)**: $C_{76}H_{25}O_{46}$ (SRIP [illegible] 1963 [illegible] 205).

[illegible] **(Tannic acid)** (**50**[illegible]) **TS**: [illegible] R [illegible] 50 [illegible] $C_{76}H_{25}O_{46}$ [illegible]

[illegible].

[illegible] **(Tartaric acid)** (**200**[illegible]) **TS**: [illegible] 200 [illegible]

$C_4H_6O_6$ [illegible].

[illegible] **RS (Testosterone enantate)**: [illegible].

[illegible] **(Tetrabutylammonium hydroxide/methanol) TS**:

Procedure [illegible]: [illegible] TS [illegible]

[illegible] 0.25 [illegible] $C_{16}H_{37}NO$ [illegible].

[illegible] **TS (Tetrabutylammonium hydroxide)**: $C_{16}H_{37}NO$.

[illegible] 400 [illegible] $C_{16}H_{37}NO$ [illegible] (~1.5 [illegible]).

[illegible] **R (Tetrahydrofuran)**: C_4H_8O.

Description [illegible]: [illegible].

Boiling point [illegible]: 66 °[illegible].

Mass density [illegible]: ρ_{20} = 0.886-0.884 [illegible].

Storage [illegible]: [illegible].

Labelling [illegible]: [illegible] 0.1% [illegible].

[illegible] **:RS (Thioacetazone)** [illegible]

[illegible] **:RS (Tiabendazol)** [illegible]

[illegible] **:R (Titanium trichloride)** [illegible] %15 [illegible]
$TiCl_3$ (SRIP 1963 [illegible] 208).

Mass density [illegible]: ~1.2 [illegible] = ρ_{20}.

[illegible] **(Titanium trichloride)** **(0.1** [illegible]**) VS:** [illegible] 100 [illegible] R 200 [illegible] (~250 [illegible]) TS [illegible]
[illegible] R 1000 [illegible].

Method of standardization [illegible] 25 [illegible] VS (0.1 [illegible]) [illegible] TS (~100 [illegible]) [illegible] R [illegible] TS (75 [illegible]) [illegible] 1 [illegible] VS (0.1 [illegible]) [illegible] 15.43 [illegible] $TiCl_3$.

[illegible] **:R (Titan yellow)** $C_{28}H_{19}N_5Na_2O_6S_4$ (SRIP 1963 [illegible] 208).

[illegible] **:TS (Titan yellow)**

Procedure [illegible]: [illegible] 0.05 [illegible] R [illegible] 100 [illegible].

[illegible] **:RS (Trihexyphenidyl hydrochloride)** [illegible]

[illegible] **:TS (Triketohydrindene/butanol)**

Procedure [illegible]: [illegible] 0.1 [illegible] R [illegible] 1-[illegible]
[illegible] 100 [illegible].

[illegible] **(Triketohydrindene hydrate)** **(1** [illegible]**) TS:** [illegible]
R [illegible] 1 [illegible] $C_9H_4O_3$ [illegible].

[illegible] **:TS (Triketohydrindene/methanol)**

Procedure [illegible]: [illegible] 1.0 [illegible] R [illegible] R [illegible]
100 [illegible].

[illegible]

[illegible] **:TS (Triketohydrindene/pyridine/acetone)**

ȸǺǼƘǤǿǟ ȸȠ ǦǿǻǺǾȠ ȳǻǅǵ ǰǺȠ ȸȠ ǾȠ 100 Ž ȸǺǼǺǿǼǼǻǻǼ ǶǻǼǻ ȸȠ ȟ 0.25 ǟǻǾǺ :*Procedure ǿǻǅǻǫǟ*

.R ȷǻǼȅȷǟȘ R

:**TS (Triketohydrindene/pyridine/acetone)** ǿǻǻǻǻ/ȸǺǼǺǻǟ/ȸǺǼǺǿǼǼǻǻǼ ǶǻǼǻ

ȸȠ ǦǼǻǾǼ ǦǼǻǾǟ ǻǾȘ R ȸǺǼƘǤǿǟ ȸȠ ǾȠ 1 Ž ȸǺǼǺǿǼǼǻǻǼ ǶǻǼǻ ȸȠ ȟ 1 ǟǻǾǺ :*Procedure ǿǻǅǻǫǟ*

.ǾȠ 100 ǯǺǾǫ R ǿǻǻǻǻǻ-1

.ǼǅǻǟǺǾ ǨǨǨǨ Ǽȥ :*ǦǻǼǻǻ*

:**TS (Triketohydrindene/stannous chloride)** ǺǺǼǾǾǟ ǼǺǿǻǻǼ/ȸǺǼǺǿǼǼǻǻǼ ǶǻǼǻ

ǿǻǾǼǻȡ ǾǼǯǼȠ ǼǼǵȘ ǨǻǾ ȸȠ ǾȠ 100 Ž R ȸǺǼǺǿǼǼǻǻǼ ǶǻǼǻ ǧǟǿǼǼ ȸȠ ȟ 4 ǟǻǾǺ :*Procedure ǿǻǅǻǫǟ*

cation ǙǟǻǻǾ ǿǺǺǦȠ ƘǺǿ ȸȠ ȟ 1 ǯȠ ǻǾǻǟ ǯǺǾ .R (ethylene glycol monomethyl ether) ƘǻǼǯǺǫǟ

Ž R ȹǺǺǼǾǾǟ ǼǺǿǻǻǼ ȸȠ ȟ 0.16 ǟǻǾǺ .(A ǿǻǻǻǟ) ǴǺǺȘ (ǺǼȠȘǺǾȠ 840-ǺǼȠȘǺǾȠ 300) exchange resin

.(B ǿǻǻ) TS Û5.5 ǿǺǼǺǟ ǯǧǺǼȅȷǟ ǦǿǿǟǻǺ ȸȠ ǾȠ 100

.ƘǿǻǻǺǟ ȸȠ ǦǿǺǺǼȠ ȳǻǅǵ ǯǺǼ ǯǧǺǻǺǦȠ ȳǟǼǺǼȅǻǟ ǾǦȩ

.(129 ǦǶǺǾǟ Û1963 ÛSRIP) C_8H_{18} Û*iso*-Octane :**R (2.2.4-Trimethylpentane)** ȷǺǼǺǟ ǾǼǯǼȠ ǶǻǼǻ-**4.2.2**

.$C_{18}H_{15}Sb$:**R (Triphenylantimony)** ȷǻǼǼǻǟ ǾǼǺǼǻ ǶǻǼǻ

.ǼǦǺǾǺ °ȳ 55 :*Melting temperature ǿǺǾǻǟ ǦǅǻǼ*

.$Na_3PO_4,12H_2O$:**R (Trisodium orthophosphate)** ȳǻǺǾǾǟ ǶǻǼǻ ǧǺǺǻǻǻǻǿȘ

.ǸǼǺ ȹǿǻǻǟ ǻǶǼȠ Ș ȷǻǻǟ ǦǻǼǯ ǧǟǿǻǻǟ :*Description ǻǾǻǟ*

ǼǼǺǼ ǶǻǺǼ Ž ȓȘ TS (ǿ/ȟ750~) ǿǻǺǯǺǫǟ Ž ǼǼǻǯ ǟǟȘǟ Ǩȡ ÜǿǺǟ Ž ȷǺǟȘǾǟ Ǻǵ :*Solubility ǦǼǺǟȘǾǟ*

.R ȷǻǟǺǾǟ

ǶǻǼǻ ǧǺǺǻǻǻǻǿȘ ǿǟ ǿǻǻ **TS** :(ǿ/ȟ2)**(Trisodium orthophosphate)** ȳǻǺǾǾǟ ǶǻǼǻ ǧǺǺǻǻǻǻǿȘ

.ǺǼǻǟ Ž Na_3PO_4 ȸȠ ȟ 2 ǦǟǺȩ ǻǯ ȹǻǼǯ ȳǻǺǾǾǟ

.1-β-D-Ribofuranosyluracil Ü$C_9H_{12}N_2O_6$:**R (Uridine)** ȸǺǼǿǻǼǟ

.ǿǺǟ Ž ǟǟȘǟ :*Solubility ǦǼǺǟȘǾǟ*

.ǼǦǺǾǺ °ȳ 165 :*Melting temperature ǿǺǾǻǟ ǦǅǻǼ*

.ǿǿǺǟ ȷǺǾȠ Ž ȷǺǻ :*Storage ȸǺǺǼǟ*

.ǦǼȘǿ ǦǼǺǼǼǻǼ ǦǼǅǻǺȠ ǵǺȠ :**RS (Valproic acid)** ǾǺȘǼǾǺǾǟ Ǹƥ

.V_2O_5 :**R (Vanadium pentoxide)** ȳȥʌẩȦφȦȦöä ǼȄÊõǗ ɄèȦⱤ

.ɄəǼò ɄøȦæ БǗ ȦȦòǗ - ɄøȦæ ȧȥɄÊɳ :*Description Ȥ òȥöä*

Ž ȦȄȲȶʒ āäşǽ Ƙɖ ÜğȦȦȥȲÖöäş gÂõȦƫä ôȥȶΣä Ž āäşǽ ÜöȦƫä Ž ȷȦäşǾöä ǴȄɄì :*Solubility ǴȄφȦäşǾöä*

.TS (ȯ/ȟ750~) ȯȥφȦǯʌqä

:**TS (Vanadium/sulfuric acid)** ȭʌøȥȦȲÊöä ȒƥȀ/ȳȥʌẩȦφȦȦöä

ȭʌøȥȦȲÊöä ȒƥȀ ȸɳ Ȫɳ 4 Ž R ȳȥʌẩȦφȦȦöä ǼȄÊõǗ ɄèȦⱤ ȸɳ ȟ 0.20 āäǾʌ :*Procedure őäȀDZqä*

.Ȫɳ 100 ɁøϘǵ őȦƫȦæ gǼʌǼì ǴȦȦȞæ ȤȦƩş TS (ȯ/ȟ1760~)

:**TS (Vanillin/hydrochloric acid)** ȭʌøȥȲõşøǼȄTä ȒƥȀ/ƙȲȄφȦȦöä

TS (ȯ/ȟ250~) ȭʌøȥȲõşøǼȄTä ȒƥȀ ȸɳ ǴȄȥȦõ ǴȄȶõ Ž R ƙȲȄφȦȦöä ȸɳ ȟ 1.0 āäǾʌ :*Procedure őäȀDZqä*

.Ȫɳ 100 ǯȦϘφq

.ȦDZāȦü TS ȭʌøȥȲõşøǼȄTä ȒƥȀ/ƙȲȄφȦȦöä ƘȒƠ Ǽƶ :*ǴȚǵȲɳ*

.ǴȄöşẩ ǴȄəȦȄȶȄõ ǴȄȞDZȀɳ gẩȦɳ :**RS (Verapamil hydrochloride)** ȪȄɳȦæäƘȦöä ǼʌøȥȲõşøǼȄȽ

.ǴȄöşẩ ǴȄəȦȄȶȄõ ǴȄȞDZȀɳ gẩȦɳ :**RS (Vincristine sulfate)** ƙȦèȀȮǼȦöä ğȦȦȲè

.ǴȄöşẩ ǴȄəȦȄȶȄõ ǴȄȞDZȀɳ gẩȦɳ :**RS (Warfarin)** ȸʌøȦȥøȥöä

.(210 ǴɄȦÔöä Û1963 ÛSRIP) $C_{13}H_{10}O_2$:**R (Xanthydrol)** ȯşøǼȄϘφäÂöä

:**TS (Xanthydrol)** ȯşøǼȄϘφäÂöä

99ş TS (ȯ/ȟ420~) ȭʌøȥȲõşøǼȄTä ȒƥȀ ȸɳ Ȫɳ 1 Ž ȯşøǼȄϘφäÂöä ȸɳ ɳȲɳ 20 āäǾʌ :*Procedure őäȀDZqä*

.TS (ȯ/ȟ300~) ȭȄϘȄèɟä ȒƥȀ ȸɳ Ȫɳ

.$Zn(C_5H_{10}NS_2)_2$:**R [Zinc bis (dibenzyldithiocarbamate)]** (ğȦɳȦæøȦõȥȄϘ ɄəȦȦϘ ȪʌÂøȦæ ɄəȦȦϘ) ȀȄæ ȭφà

.ȒȄæǗ Ƀøȥȳæ ȧȥɄÊɳ :*Description Ȥ òȥöä*

.R ȳøȥȥşøȥȲȮöä Ž āäşǽ :*Solubility ǴȄφȦäşǾöä*

.°ȳ 180-178 :*Melting range øȦȚÔφɍä òȦƒ*

:**TS [Zinc bis (dibenzyldithiocarbamate)]** (ğȦɳȦæøȦõȥȄϘ ɄəȦȦϘ ȪʌÂøȦæ ɄəȦȦϘ) ȀȄæ ȭφà

ȸɳ ǴȄȥȦõ ǴȄȶõ Ž R (ğȦɳȦæøȦõ ȥȄϘ ɄəȦȦϘ ȪʌÂøȦæ ɄəȦȦϘ) ȀȄæ ȭφà ȸɳ ɳȲɳ 10.0 āäǾʌ :*Procedure* őäȀDZqä

.Ȫɳ 100 ǯȦϘφq R ȷȥæȀȮöä ǼʌøȥȲõ Ʉʒȧæø

.ǴȄöşẩ ǴȄəȦȄȶȄõ ǴȄȞDZȀɳ gẩȦɳ :**RS** (ƙȦȄɳȥȲȮöä ğäȀϘȄÊö **Z-**ȟşȦÔƫä) **(Zuclomifine)** ƙȦȄɳȥȲõşÂöä